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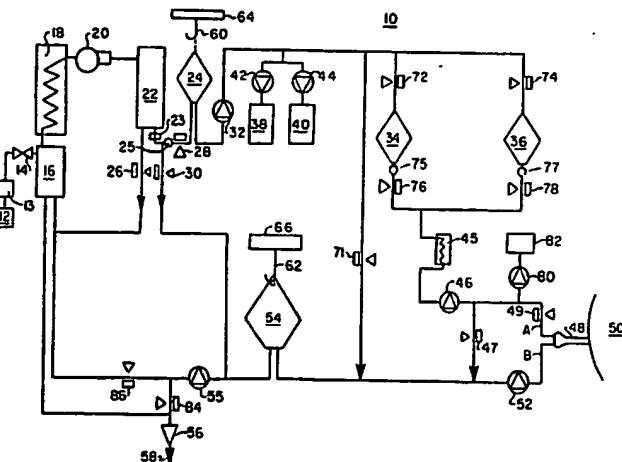
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(54) Title: MEDICAL DRUG FORMULATION AND DELIVERY SYSTEM

(57) Abstract

Medical drug formulation and delivery system includes a reverse osmosis device for purifying water from a source comprising a housing having an inlet for passage of water from the source, a first outlet for passage of purified water from the housing and a second outlet for passage of waste water remaining after purification. A first reverse osmosis multilayer assembly is disposed within the housing in fluid communication with the inlet for purification of at least a first portion of the water from the source. Water treatment chemicals can be positioned in a core about which the first reverse osmosis multilayer assembly is wound. The treatment chemicals are in fluid communication with the first reverse osmosis multilayer assembly to receive the first purified portion of water and for removal of at least chemical contaminants therefrom. A second reverse osmosis multilayer assembly is also wound on the core and is in fluid communication with the water treatment chemicals to receive the chemically purified water for purification of at least a second portion thereof. The second reverse osmosis multilayer assembly is in fluid communication with the first outlet so as to permit passage of the second portion of purified water therethrough. In one preferred embodiment, the first and second reverse osmosis assemblies are formed integrally in a side by side configuration. In an alternative embodiment, they are rolled about the core in an interleaved configuration. A method of forming a reverse osmosis device, a peritoneal dialysis treatment system and alternative treatment systems incorporating such a device as well as corresponding methods of treatment are also disclosed.



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## MEDICAL DRUG FORMULATION AND DELIVERY SYSTEM

The present invention relates to a device for purifying fluids and in particular to a reverse osmosis device for use, for example, in sterilizing and purifying fluids serially through at least two reverse osmosis stages, for use in a system for medical drug formulation and delivery and for other end use applications.

### BACKGROUND OF THE INVENTION

10       The purification or separation of fluids using synthetic membranes can be advantageously used in many industrial, medical and home applications. Typical membrane separation processes include gas and vapor diffusion, dialysis, ultrafiltration and reverse osmosis.

15       Synthetic polymeric membranes can be applied to gaseous systems to separate gaseous solutions into their components. The membrane used in the gaseous systems must be permeable and selective, possess chemical and physical stability and be free of structural irregularities such as pinholes. The containing vessel should be capable of supporting these membranes under large pressure differentials; have a large membrane surface area per unit volume; cause a minimum pressure drop in the gas streams; and be inexpensive, i.e., be constructed of low-cost materials which are easy to fabricate and assemble. An example of such gas separation using synthetic membranes is the recovery of helium from natural gas and of oxygen from air. Such membrane separation processes, however, are often not competitive to known cryogenic processes because of the high power requirements for membrane separation.

20       Synthetic polymeric membranes have been applied to dialysis wherein some solutes selectively permeate through the membrane based on the concentration gradient across the membrane. While the dialysis process is not particularly

rapid, it has been industrially utilized, for example, in the recovery of caustic from rayon and the recovery of spent acid from metallurgical liquors.

Ultrafiltration typically involves the separation of large solute particles from the solvent of the solution by forcing the solvent to pass through a membrane while the particles are retained to a greater or lesser extent. Often the separation involves a physical sieving of the particles which are retained on top of the membrane filter. For membranes of low pore radius, however, the process of ultrafiltration begins to overlap the process of reverse osmosis wherein the physical sieving phenomena is increasingly replaced with the adsorption and solubility of the solute within the membrane. The retained solutes consequently can have significant osmotic pressures which must be overcome by higher fluid pressures.

Hemodialysis is an example of a dialysis process which is assisted by ultrafiltration. A hemodialyzer is a membrane-containing device which is able to remove certain waste products such as urea, creatinine and uric acid from the blood. The patient's blood is introduced into the hemodialyzer preferably under the patient's own perfusion pressure and flows past the membrane which is typically cellulose. The blood solutes containing the waste then permeate through the membrane and into the dialysate, a sterilized solution formulated to control solute permeability through the membrane. Because osmosis may result in the undesirable net transfer of water from the dialysate into the blood which may result in edema, hemodialysis is often utilized in conjunction with ultrafiltration to remove the excess water. The dialysate can be prepared by the combination of purified water, produced by reverse osmosis, and the desired concentrate.

Reverse osmosis using synthetic polymeric membranes has been used for a variety of industrial end products. Such processes include the desalination of sea water and the processing of food and beverages. The alternative method of processing is by distillation. However, because of the high energy requirements of distillation, reverse osmosis processes compare favorably as the most economic route. Furthermore, for solutions susceptible to degradation at high temperatures such as fruit juices, reverse osmosis may be the most practical manner of processing the solutions while preventing substantial loss of desirable components in the original solutions.

An important use of the reverse osmosis process in the medical field is its application to peritoneal dialysis therapy. A generalized discussion of peritoneal dialysis therapy is discussed and described in U.S. Patent No. 4,239,041 to Popovich et al. In particular, the Popovich patent discusses a fluid infusion method for continuous, ambulatory peritoneal dialysis (CAPD). The CAPD process differs from the more popular hemodialysis process in that it utilizes the body's natural peritoneal membrane in order to provide for the function of the artificial kidney. The CAPD process, however, while being ambulatory, is performed during the patient's normal, daily routine and requires treatment several times during the day. For this reason, the patient must remain by the dialysate supply during the entire period of treatment. This obviously will conflict with the patient's daytime activities and/or job requirements.

Alternatively, peritoneal dialysis can be performed at a hospital or clinic which requires that the patient visit the facility in order to obtain the required treatment. Such a visit requirement also has its inherent limitations on the normal activities of the patient.

Peritoneal dialysis is also generally discussed and described in the "Handbook 6010, Automated Peritoneal Dialysis", 1979 which is incorporated herein by reference. This handbook was distributed by B-D Drake Willock, a division of Becton, Dickenson and Co. in New Jersey and discusses that dialysate which is prepared from purified water can be infused into the patient's peritoneum through a catheter. Dialysis of the patient's blood through the peritoneal membrane and into the purified water region then occurs, allowing the body to excrete water, metabolites and toxins, and to regulate fluid, electrolyte and acid-base balance. The waste dialysate is subsequently drained out of the body. Peritoneal dialysis can be performed by various methods such as continuous and intermittent, as explained in Miller et al. "Automated Peritoneal Dialysis Analysis of Several Methods of Peritoneal Dialysis", Vol. XII Trans. Amer. Soc. Artif. Int. Organs p. 98 (1966).

Problems related to peritoneal dialysis include the difficulty in maintaining sterile conditions so as to prevent infection and the complexity of operating currently available peritoneal dialysis systems. A peritoneal dialysis device manufactured by Physio-Control Corporation of Redmond, Washington is generally described in "PDS 400 Service Manual P/N 10454-01 July, 1981" which is also incorporated herein by reference. The device purifies the source water using a reverse osmosis module which is formed of a plastic housing containing a spiral wound membrane of cellulose triacetate. The device mixes the purified water with concentrate to form a dialysate, and then delivers the dialysate to the patient. The system controls the dialysate delivery at a set inflow rate and period and a set outflow period. An alarm is sounded and the system is turned off if various parameters are not within the set ranges. The parameters include the dialysate temperature, the dialysate conductivity, the inflow and outflow volume, and the system overpressure. The

Physio-Control device is made up of two subsystems; the RO unit and the proportioning and monitoring unit. The device is bulky and complex in operation and requires extensive training of either the medical personnel or the patient that operate it. Additionally, extensive preventive maintenance is required to keep the system operational. Such maintenance includes the replacement of the RO pre-filter, filters and O-rings within the device every 500 hours of use as well as the cleaning of the RO sump pump. In addition, the device requires cleansing with bleach every 100 hours. Moreover, an extensive disinfection with formaldehyde must be performed before patient use if the sterile path has been broken during the functional test, calibration or adjustment of the device.

Another peritoneal dialysis device was designed by Ramot Purotech Ltd. The device employs RO membrane filtration through an RO cell formed of a large number of small membranes supported on plastic plates. After mixing the filtered water with concentrate to form the dialysate, the dialysate is fed by gravity to the patient. The outflow from the patient is also done by gravity into a waste bag. The need to connect the dialysate to the patient, leads to difficulties in maintaining sterile conditions.

Yet another peritoneal dialysis system is disclosed in U.S. Patent No. 4,586,920; 4,718,890; and 4,747,822 to Peabody. The patents recite a continuous flow peritoneal dialysis system and process in which a continuous flow of sterile dialysis fluid is produced and caused to flow through the peritoneal cavity of the patient in a single-pass open circuit. A gravity fed system is utilized to flow the fluid into the patient's peritoneum. The pressure of the peritoneum and the volume of fluid into the peritoneum are monitored to ensure efficient and comfortable peritoneal dialysis. The pressure monitors of the system are capable of controlling the flow of fluid into the peritoneum. This system, however similar to others previously discussed, does

not address the manner in which sterile conditions may be maintained nor the daunting complexity of operation required to be performed by the patient or care giver to use and maintain the system.

These and other problems have been solved in part  
5 by another device for peritoneal dialysis treatment called  
the Inpersol Cycler™ 1000, the Handbook of which is  
incorporated herein by reference. The Cycler™ is used to  
perform peritoneal dialysis in continuous cycling peritoneal  
dialysis (CCPD) and intermittent peritoneal dialysis (IPD)  
10 applications. The Cycler™ 3000 is used to not only perform  
CCPD and IPD but also tidal peritoneal dialysis (TPD). The  
Cycler™ is portable and is designed to be used in the home as  
well as in the clinic or hospital. In typical CCPD  
15 applications the exchanges are made at night while the  
patient is sleeping. A portion of the final dose is retained  
in the peritoneum during the day and drained out at the  
beginning of the nightly exchanges. The cycler system  
includes the cycler control unit and the stand. The stand  
holds the cycler unit, and fresh and spent dialysis fluids.  
20 The cycler control unit contains the warmer, weighing system,  
valving system and control electronics.

Notwithstanding the Cycler™, the problems of other  
known peritoneal dialysis devices have been solved by the  
present invention which is directed to a reverse osmosis (RO)  
25 filtration device for purifying water and for use in a user  
friendly automatic home dialysis system which will permit the  
patient to obtain peritoneal dialysis during sleeping hours.  
In this fashion, the patient will be free to conduct his  
normal activities during his waking or business hours without  
30 the interference of dialysis treatment. Additionally, the RO  
device and system of the present invention provide a self-  
contained, compact and sophisticated system whereby  
peritoneal dialysis is automatically performed and  
35 continuously controlled so as to allow the patient to undergo

peritoneal dialysis at home with minimal need for patient intervention. This permits the patient to lead a more natural and fuller life than permitted under known treatment procedures.

The RO device and system of the present invention also provide for a low cost, efficient means to produce solutions of sufficient sterility, low pyrogen content and low dissolved mineral content for many other industrial and medical applications. Because of the compactness of the apparatus and its ease of use, purified fluids such as sterile and pyrogen-free water can be produced on site as needed without the inconvenience and cost of storing large quantities of the purified fluid. When applied to purifying water, the invention produces water of sufficient sterility such that the purified water can be employed in peritoneal dialysis, irrigation of patients during surgery or postoperative therapy, and pharmaceutical production for oral and intravenous administration. Additionally, the RO device can produce sterile water for the formulation of dialysate solution required in hemodialysis treatment. The purified water as produced by the device and system of the present invention can satisfy U.S.P. requirements as presented in the United States Pharmacopeia, The National Formulary P1456-1574, 1596-1598, 1705-1710, January 1, 1990, US PXXII United States Pharmacopeial Convention, Inc. Also, the RO device and system avoids any need for terminal sterilization as required by known peritoneal dialysis devices.

Alternatively, the RO device and system of the present invention may be adapted to supply sterile water for the formulation of dialysate for use in hemodialyzers. The hemodialyzers in turn use the dialysate to purify the patient's blood in a manner currently used in hospitals and clinics.

For less demanding processes where sterility is not a major concern, the RO device and/or system of the present invention may be adapted to dialysis and ultrafiltration processes. Typical end use applications include those previously discussed such as the recovery of spent caustic or acid solutions from industrial production liquors (i.e. rayon steep liquor and metallurgical liquor).

The present invention is also directed toward the method of manufacturing the RO device in a manner which would minimize the cost of manufacturing and expedite it as well. Assembly steps include the application of adhesive in an automated manner by roller coating, induction bonding, sonic welding, and radiation sterilization.

#### SUMMARY OF THE INVENTION

The present invention is directed to an apparatus for purifying fluid from a source comprising first reverse osmosis means adapted for fluid communication with the source for purification of at least a portion of the fluid from the source; and second reverse osmosis means being in fluid communication with the first reverse osmosis means to receive at least some of the purified portion of fluid for further purification of at least a further portion of the fluid.

The fluid may be in the liquid or gaseous state. The configuration of the reverse osmosis means includes reverse osmosis multilayer assemblies which are either spirally wound or stacked in a parallel leaf configuration. Alternatively, the reverse osmosis means is in the form of hollow non-porous semipermeable membrane fibers composed of synthetic membrane. Synthetic membranes useful for reverse osmosis include cellulose nitrate, cellulose acetate, polyamides, polyimides, polytetrafluoroethylene, poly-(vinyl chloride) and polysulfone.

Preferably the RO apparatus is for use with a potable water source and the first reverse osmosis means comprises a first reverse osmosis multilayer assembly spirally rolled about a first axis so as to provide a generally spiral flow path of the water from the source. The 5 second reverse osmosis multilayer assembly is spirally rolled about a second axis so as to provide a generally spiral flow path for at least some of the purified first portion of water from the first reverse osmosis means.

Preferably, the first and said second reverse 10 osmosis multilayer assemblies are formed integrally and the first axis and the second axis are co-linear. A separator means is disposed so as to fluidly separate the integral multilayer assembly when rolled about its axis into the first and the second reverse osmosis multilayer assemblies.

15 In one embodiment, the separator means is an impermeable adhesive. Also the integral multilayer assembly comprises first reverse osmosis membrane layer; porous mesh layer; second reverse osmosis membrane layer; and porous permeate layer. A container can enclose either the first or 20 the second reverse osmosis multilayer assembly.

In an alternative embodiment, the first reverse osmosis means is disposed in an interleaf configuration with the second reverse osmosis means and each comprises at least a reverse osmosis multilayer assembly spirally rolled about a 25 common axis. Preferably, the first reverse osmosis multilayer assembly comprises first reverse osmosis membrane layer; porous mesh layer; second reverse osmosis membrane layer; and first porous permeate layer. The second reverse osmosis multilayer assembly comprises third reverse osmosis 30 membrane layer; second porous permeate layer; fourth reverse osmosis membrane layer; and third porous permeate layer.

The present invention is also directed to a method for purifying fluid from a source comprising passing fluid from the source through a first reverse osmosis means being 35

in fluid communication with the source so as to purify at least a portion of the fluid from the source; and passing the purified first portion of fluid through a second reverse osmosis means being in fluid communication with the first reverse osmosis means to receive the purified portion of water for further purification of the fluid. Preferably, the fluid can be water.

According to another embodiment, the present invention is directed to an apparatus for purifying water from a source comprising housing having an inlet for passage of water from a source, a first outlet for passage of purified water from the housing and a second outlet for passage of waste water remaining after purification; first reverse osmosis means disposed within said housing and being in fluid communication with the inlet for purification of at least a first portion of the water from the source; the first reverse osmosis means also being in fluid communication with the second outlet for passage of waste water through the second outlet; chemical purification means being in fluid communication with the first reverse osmosis means to receive the first purified portion of water and for removal of at least chemical contaminants from the first purified portion of water; and second reverse osmosis means being in fluid communication with the chemical means to receive the chemically purified water for purification of at least a second portion of the chemically purified water, the second reverse osmosis means also being in fluid communication with the first outlet so as to permit passage of the second portion of purified water through the first outlet.

In one embodiment, the housing further comprises a third outlet for passage of waste water remaining after purification, and the first reverse osmosis means is in fluid communication with the third outlet so as to permit passage of waste water through the third outlet. The second

reverse osmosis means is in fluid communication with the second outlet so as to permit passage of waste water through the second outlet.

The housing is formed of a material possessing sufficient structural integrity to withstand the pressure requirements of the reverse osmosis process. The material may be but is not limited to steel, aluminum, fiberglass and Kevlar®. Also, the housing includes an elongated hollow cylindrical container having a base and an open end and includes a cap configured and dimensioned to seal the open end in a fluid tight configuration. The cap has an inlet passageway for admitting water from the source, a first passageway for purified water and a second passageway for waste water. A third outlet passageway could also be provided for passage of waste water. A generally cylindrical core is disposed within the housing and extends from the base to the cap. The integral multilayer assembly is rolled about the outer surface of the cylindrical core so as to provide for spiral flow paths of the water to be purified. The cylindrical core has a hollow central portion and the chemical means is disposed within the hollow central portion. The chemical means includes but is not limited to diatomaceous earth, clay, ion exchange resins, activated carbon or other similar material and mixtures thereof. The chemical means provides a variety of functions including the removal of dissolved gases and chloramine contaminants. Filter plugs are disposed at the ends of the hollow central portion so as to contain the chemical means therebetween. The apparatus further comprises a second cylindrical hollow container having a base and an open end and is configured and dimensioned so as to be adapted to be positioned within the first container and to receive and to seal the second reverse osmosis means therein. At least one O ring or other sealing means is disposed between the open end of the second cylindrical hollow container and the impermeable adhesive

disposed along the central portion of the integral multilayer assembly so as to aid in sealing the first osmosis means within the second container.

Preferably, the integral multilayer assembly comprises first reverse osmosis membrane layer; porous mesh layer; second reverse osmosis membrane layer; and porous permeate layer. Also, the first and said second reverse osmosis membrane layers each comprises nonporous semi-permeable membrane layer; porous ultrafiltration layer; and porous support layer. The semi-permeable membrane layer is formed generally of a solid nonporous continuous thin polymeric composition and the porous support layer is formed generally of polyamide which can be either of a woven or non-woven configuration.

After being rolled about the outer surface of the cylindrical core, the reverse osmosis multilayer assembly generally includes in a radially outwardly configuration from the surface, the porous permeate layer, the second reverse osmosis membrane layer, the porous mesh layer and the first reverse osmosis membrane layer. Preferably, the nonporous semi-permeable membrane layers of the first and the second reverse osmosis membrane layers are disposed adjacent the porous mesh layer.

In another preferred embodiment of the present invention, the apparatus has a second reverse osmosis means being in fluid communication with the first reverse osmosis means to receive the first purified portion of water for purification of at least a second portion of the purified water, the second reverse osmosis means also being in fluid communication with the second outlet for passage of waste water through the second outlet. Chemical means in fluid communication with the second reverse osmosis means receives the second purified portion of water and removes at least chemical contaminants from the second purified portion of

water. The chemical means is also in fluid communication with the first outlet so as to permit passage of the second portion of purified water through the first outlet.

In this embodiment, the first reverse osmosis means is disposed in an interleaved configuration with the second reverse osmosis means. The first reverse osmosis means comprises at least a first reverse osmosis multilayer assembly and the second reverse osmosis means comprises at least a second reverse osmosis multilayer assembly. Both the first and the second reverse osmosis multilayer assemblies are spirally rolled about a common axis. The first reverse osmosis multilayer assembly comprises first reverse osmosis membrane layer; porous mesh layer; second reverse osmosis membrane layer; and first porous permeate layer. Also, the second reverse osmosis multilayer assembly comprises third reverse osmosis membrane layer; second porous permeate layer; fourth reverse osmosis membrane layer; and third porous permeate layer.

Preferably, the first, second, third and fourth reverse osmosis membrane layers each comprises nonporous semi-permeable membrane layer; porous ultrafiltration layer; and porous support layer. The semi-permeable membrane layer is formed generally of a solid nonporous continuous thin polymeric composition such as polyamide. The porous support layer can be made of polyamide. The polyamide can be of a woven or non-woven configuration.

After the reverse osmosis multilayer assemblies are rolled about the outer surface of the cylindrical core, they include in a radially outwardly configuration from the surface, the third porous permeate layer, the fourth reverse osmosis membrane layer, the second porous permeate layer, the third reverse osmosis membrane layer, the first porous permeate layer, the second reverse osmosis membrane layer, the porous mesh layer and the first reverse osmosis membrane layer.

The nonporous semi-permeable membrane layers of the first and the second reverse osmosis membrane layers are disposed adjacent the porous mesh layer. Preferably, the nonporous semi-permeable membrane layers of the third and the fourth reverse osmosis membrane layers are disposed adjacent the second porous permeate layer.

In an alternative embodiment for purifying water from a source, the method comprises passing water from the source through a first reverse osmosis means being in fluid communication with the source so as to purify at least a first portion of the water from the source; passing the purified first portion of water through chemical means being in fluid communication with the first reverse osmosis means to receive the first purified portion of water and for removal of at least chemical contaminants from the first purified portion of water; and passing the chemically purified water through a second reverse osmosis means being in fluid communication with the chemical means to receive the chemically purified water for purification of at least a second portion of the chemically purified water, the second reverse osmosis means also being in fluid communication with the first outlet and the second outlet so as to permit passage of the second portion of purified water through the first outlet and for passage of waste water through the second outlet.

In yet another preferred embodiment, after passing water from the source through a first reverse osmosis means so as to purify at least a first portion of the water from the source, the method comprises passing the purified first portion of water through a second reverse osmosis means being in fluid communication with the first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; and passing the purified second portion of water through chemical means being in fluid communication with the second reverse

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osmosis means to receive the second purified portion of water and for removal of at least chemical contaminants from the purified second portion of water, the chemical means also being in fluid communication with the first outlet so as to permit passage of the chemically purified water through the first outlet. If desired, the purified water can be passed through a filtration means for further purification.

10

The present invention also is directed to a peritoneal dialysis system for treating a patient comprising reverse osmosis device for purifying water from a source and having input means for coupling to the source of water; first reverse osmosis means being in fluid communication with the input means for purification of at least a first portion of the water from the source; and second reverse osmosis means being in fluid communication with the first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; means for supplying a predetermined amount of drug and means for mixing the purified second portion of the fluid with the concentrate to provide a dialysate solution; and

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means for delivering the dialysate solution to the peritoneal cavity of the patient.

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The system further comprises means for draining waste water from the reverse osmosis device and also means for draining spent dialysate solution from the peritoneal cavity of the patient.

25

The delivering means can be adapted to include, but not be limited to, continuous, intermittent, tidal or continuous ambulatory peritoneal dialysis treatment of the patient as well as other treatments including hemodialysis.

30

The system further comprises means for heating the water from the source. The water can be heated up to about 70°C, preferably up to about 50°C, for example up to 36°C, to increase the efficiency of the reverse osmosis device. The heating means is coupled to the input means of the reverse

osmosis device so as to heat the water before purification. A high pressure pump can be fluidly coupled between the heater means and the reverse osmosis device so as to provide sufficient pressure to allow for proper operation of the reverse osmosis device. The reverse osmosis device further includes a first outlet for passage of purified water from the second reverse osmosis means and a second outlet for passage of waste water remaining after purification. The reverse osmosis device can further comprise a third outlet in fluid communication with the first reverse osmosis means so as to permit passage of waste water through the third outlet.

Also, a heat exchanger means can be fluidly coupled to the second outlet of the reverse osmosis device and can be disposed in thermal relationship with the water from the source so as to provide for transfer of heat from the waste water to the water to be heated. Also heat exchanger means can be fluidly coupled to the means for draining spent dialysate solution and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from the solution to the water to be heated. The supplying means comprises a storage bag having a coupling end and containing a predetermined drug and a metering system such as a syringe or a precision pump in fluid communication with the coupling end of the storage container to receive a predetermined amount of drug and also is in fluid communication with the purified second portion of the water after passing through the first outlet.

The system further comprises means for sterilizing the coupling end of the storage container when being coupled and decoupled to the metering system.

The mixing means is in fluid communication with the first outlet and the metering means so as to receive the purified second portion of the water and the predetermined

amount of drug for preparation of a dialysate solution. The mixing means can be any of an ultrasonic, electromechanical, electromagnetic or static mixer.

In one alternative embodiment, the delivery means comprises a dual lumen catheter affixed to the patient and adapted for fluid communication at one end of one lumen with the peritoneal cavity of the patient and at the other end of the one lumen with the mixing means so as to allow for delivery of the dialysate solution to the peritoneal cavity. The other lumen is adapted for fluid communication with the peritoneal cavity of the patient at one end and at the other end with a drain means to receive the spent dialysate solution from the peritoneal cavity.

In another embodiment, the delivery means comprises a single lumen catheter affixed to the patient and adapted for fluid communication at one end of the lumen with the peritoneal cavity of the patient and at the other end of the lumen with the mixing means so as to allow for delivery of the dialysate solution to the peritoneal cavity. A pump can be fluidly coupled, as desired, between the supplying means and the reverse osmosis device, between the mixing means and the peritoneal cavity of the patient, and between the peritoneal cavity of the patient and an isolation valve and a drain means for receiving the used dialysate solution. Also, a computer can be employed for predetermined, selective and automatic control of the delivery means. The system can further comprise chemical means positioned in fluid communication with the second reverse osmosis means to receive said second purified portion of water and for removal of at least chemical contaminants from the second purified portion of water.

A method for treating a patient comprises purifying water from a source with a reverse osmosis device having input means for coupling to the source of water; first reverse osmosis means being in fluid communication with the

input means for purification of at least a first portion of the water from the source; and second reverse osmosis means being in fluid communication with the first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; supplying a predetermined amount of drug; mixing the drug with the purified second portion of the water so as to provide a dialysate solution; and delivering the dialysate solution to the peritoneal cavity of the patient. The delivery of the dialysate solution can be continuous,  
5 intermittent, of the tidal mode of treatment or of the continuous ambulatory mode of treatment. Preferably, the water is heated and is pumped under a predetermined pressure prior to purification.

Also, at least a portion of the waste water from  
15 the reverse osmosis device can be returned to a heat exchanger means disposed in thermal relationship with the water from the source so as to provide for transfer of heat from the waste water to the water to be heated. At least a portion of the spent dialysate solution can be returned to a heat exchanger means disposed in thermal relationship with the water from the source so as to provide for transfer of heat from the dialysate solution to the water to be heated.  
20 Moreover, the first purified portion of water can be passed through chemical means being in fluid communication with the first reverse osmosis means for removal of at least chemical contaminants from the first purified portion of water before passing on to the second reverse osmosis means.  
25 Alternatively, the second purified portion of water can be passed through chemical means being in fluid communication with the second reverse osmosis means for removal of at least chemical contaminants from the second purified portion of water. Also the chemically treated water portion can be passed through a filtration means fluidly coupled to the  
30 chemical means for further purification of the water portion.  
35

The method further comprises draining waste water from the reverse osmosis device. Also the method can further comprise draining spent dialysate solution from the peritoneal cavity of the patient.

5 Another system for supplying purified water from a source comprises a reverse osmosis device according to the present invention and means for delivering the purified second portion of the water to either a storage means for future use or to a control means for immediate predetermined use.

10 The present invention is moreover directed to a hemodialysis system for treating a patient comprising reverse osmosis device for purifying water from a source and having input means for coupling to the source of water; first reverse osmosis means being in fluid communication with the input means for purification of at least a first portion of the water from the source; and second reverse osmosis means being in fluid communication with the first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; and means for supplying a predetermined amount of 15 drug; means for mixing the purified second portion of the water with the drug to provide a dialysate solution; and means for delivering the dialysate solution to a hemodialyzer. The system further comprises means for draining waste water from the reverse osmosis device and also 20 means for draining spent dialysate solution from the hemodialyzer. The reverse osmosis device further comprises chemical means being in fluid communication with the first reverse osmosis means to receive the first purified portion of water and for removal of at least chemical contaminants 25 from the first purified portion of water before passing on to the second reverse osmosis means. Means for heating the water from the source is provided and is coupled to the input means of the reverse osmosis device so as to heat the water 30

before purification. A high pressure pump is fluidly coupled between the source and the reverse osmosis device so as to provide sufficient pressure to allow for proper operation of the reverse osmosis device. The system further comprises means for heating the water from the source which is fluidly coupled between the high pressure pump and the source so as to heat the water before purification. The means for heating the water from the source can also be fluidly coupled between the high pressure pump and the reverse osmosis device so as to heat the water before purification. The reverse osmosis device further includes a first outlet for passage of purified water from the second reverse osmosis means and a second outlet for passage of waste water. The reverse osmosis device further comprises a third outlet for passage of waste water. The apparatus first osmosis means is in fluid communication with the third outlet so as to permit passage of waste water through the third outlet. The second reverse osmosis means is in fluid communication with the second outlet for passage of waste water through the second outlet. A heat exchanger means is fluidly coupled to the second and/or third outlet of the reverse osmosis device and is disposed in thermal relationship with the water from the source so as to provide for transfer of heat from the waste water to the water to be heated. Alternatively, the heat exchanger means can be fluidly coupled to the means for draining spent dialysate solution and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from the solution to the water to be heated.

According to the system, the supplying means comprises a storage container having a coupling end and containing a predetermined drug, and a metering system in fluid communication with the coupling end of the storage container to receive a predetermined amount of drug and is further in fluid communication with the purified second

portion of the water after passing through the first outlet. The system further comprises means for sterilizing the coupling end of the storage container when being coupled and decoupled to the metering system. The mixing means is in fluid communication with the first outlet and the metering system so as to receive the purified second portion of the water and the predetermined amount of drug for preparation of a dialysate solution. The mixing means can be an ultrasonic, electromagnetic, electromechanical or a static mixer. Pump means is fluidly coupled between the supplying means and the reverse osmosis device. Pump means can also be fluidly coupled between the mixing means and the hemodialyzer, and also between the hemodialyzer and a drain means for receiving the spent dialysate solution. A computer means provides for predetermined, selective and automatic control of the delivery means, the supplying means, the mixing means and the draining means.

The present invention is also directed to a system for irrigating a portion of a patient's body comprising a reverse osmosis device according to the present invention and means for supplying the purified second portion of the water to the portion of the patient's body. The system can further comprise means for supplying a predetermined amount of drug; means for mixing the purified second portion of the water with the drug to provide a drug solution; and means for delivering the drug solution to the portion of the patient's body. The supplying means is adapted for irrigating a wound or a cavity of a patient with the drug mixture. The supplying means can also include a humidifying means which is adapted for humidification of a patient's lungs.

In addition, the present invention is directed to a system for delivery of a predetermined injectable drug to a patient comprising a reverse osmosis device according to the present invention; means for supplying and mixing the

predetermined drug with the purified second portion of water; and means for supplying the said drug and purified water mixture to a body portion of the patient.

A heat exchanger according to the present invention for transferring heat to a first source of fluid from a second source of fluid comprises an elongated core; first film composite having a first porous mesh and a first fluidly impermeable layer; second film composite having a second porous mesh and a second fluidly impermeable layer; the first and the second film composites being disposed in an interleaved configuration and being disposed about the core so as to provide a first fluid flow path generally between the core and the first fluidly impermeable layer and a second fluid flow path between the first fluidly impermeable layer and the second fluidly impermeable layer such that heat from fluid in one of the first and the second flow paths can be transferred to the fluid in the other flow path.

The core is generally cylindrical and the first and the second film composites are generally rectangular and are spirally rolled about the core. The first and the second fluidly impermeable layers are each formed of a metallic foil, an impermeable polymeric film, or an impermeable inorganic film. The heat exchanger further comprises means for fluidly sealing the first and the second film composites along one edge to the core and also sealing to the core the adjacent edges transverse to the one edge. Preferably the sealing means comprises an impermeable adhesive. The heat exchanger further comprises an elongated hollow cylindrical housing container having a base and an open end. The housing container includes a cap configured and dimensioned to fluidly seal the open end and includes an inlet passageway for admitting fluid from the first source, a first outlet for passage of the first source after heating, a second inlet for

passage of said second source and a second outlet for passage of the second source after transfer of heat to the first source.

In one embodiment, the first inlet and the first outlet are in fluid communication with the first fluid path, and the second inlet and second outlet are in fluid communication with the second fluid path.

A peritoneal dialysis system according to the present invention for treating a patient comprises a reverse osmosis device for purifying water according to the present invention wherein the reverse osmosis device is formed of radiation sterilizable components; means for supplying a predetermined amount of drug; means for mixing the purified second portion of the water with the drug to provide a dialysate solution; and means for delivering the dialysate solution to the peritoneal cavity of the patient. The supplying means is selectively replacable in the system and is adapted for maintaining sterile fluid couplings and decouplings in the system. Similarly, the mixing means and delivering means are adapted for maintaining sterile fluid couplings and decouplings in the system. The system further comprises means for draining spent dialysate solution from the peritoneal cavity of the patient. The draining means includes a one way isolation valve to prevent any retrograde biocontamination of the peritoneal cavity of the patient.

In one embodiment, the supplying means comprises a storage container having a coupling end and containing a predetermined drug, and a metering system in fluid communication with the coupling end of the storage container to receive a predetermined amount of drug and further is in fluid communication with the purified second portion of the water after passing through the first outlet. The system further comprises means for sterilizing the coupling end of the storage container when coupled and decoupled to the metering system. Preferably, the mixing means is in fluid

communication with the first outlet and the metering system so as to receive the purified second portion of the water and the predetermined amount of drug for preparation of a dialysate solution. The system further comprises first pump means fluidly coupled between the mixing means and the reverse osmosis device, second pump means fluidly coupled between the mixing means and the supplying means, third pump means adapted to be fluidly coupled between the mixing means and the peritoneal cavity of the patient and fourth pump means adapted for fluid coupling between the peritoneal cavity of the patient and a drain means for receiving the used dialysate solution. The first, second, third and fourth pump means comprise volumetric pumps which are calibratable. A second supplying means is adapted for fluid coupling to the peritoneal cavity of the patient for selective admission of a second predetermined drug. A fifth pump means is adapted for fluid coupling between the second supplying means and the peritoneal cavity of the patient. Also, the fifth pump means comprises a volumetric calibratable pump.

The system further comprises clamp means for selective and independent operation of the components of the system. The clamp means comprises a plurality of on-off clamps disposed at predetermined fluid positions of the system. A computer means is coupled to the plurality of on-off claims for automatic predetermined operation thereof.

The housing of the reverse osmosis device includes an elongated hollow first cylindrical container having a base and an open end. A generally cylindrical core is disposed within the housing and extends from the base to the cap. The first and second reverse osmosis means are rolled about the outer surface of the cylindrical core so as to provide for spiral flow paths of the water to be processed. The cylindrical core has a hollow central portion for receiving chemical means within the hollow central portion. The system further comprises a second cylindrical hollow container

having a base and an open end and which is configured and dimensioned so as to be adapted to be positioned within the first container, and to receive and to seal the first reverse osmosis means therein. The housing includes a cap configured and dimensioned to fluidly seal the open end and includes an inlet passageway for admitting water from the source, a first outlet passageway for purified water and a second outlet passageway for waste water. The cap has an inner face and an outer face and further comprises a plurality of protrusions extending from the inner face into selective contacting relationship with the core at predetermined positions. The protrusions are fusible with the core upon application of at least one of ultrasonic and thermal energy. Also, the second cylindrical container has an inner face and further comprises a plurality of protrusions extending from the inner face into selective contacting relationship with the core at predetermined positions. The core has a plurality of passageways predeterminately coupled through the inner face of the cap and the inner face of the second container to provide fluid flow paths for the water from the source, the waste water and the purified water into, through and out of the housing.

The system comprises at least a first conductivity sensor disposed downstream of said source of purified water for monitoring of the conductivity of said water. A second conductivity sensor is disposed downstream of the mixing means for monitoring of the conductivity of the dialysate solution.

The system further comprises means for restricting the flow of water therethrough and also thereby through the reverse osmosis device. The flow restricting means comprises a flow plug configured and dimensioned so as to be adapted to be disposed within at least one passageway in the core. The flow plug has a reduced effective cross sectional area than the at least one passageway so as to restrict the flow of

water through the passageway and provide for predetermined pressures on either side of the flow plug. Preferably, at least two flow plugs are disposed in a different passageway in the core. A computer means is coupled to the first and the second conductivity sensors for selective, predetermined operation of the system.

A method of manufacturing a reverse osmosis device on a core for purifying water from a source comprises providing an integral reverse osmosis multilayer assembly having first reverse osmosis membrane layer; porous mesh layer; second reverse osmosis membrane layer; and porous permeate layer; sealing a central portion of the integral multilayer assembly; sealing at least one edge of the multilayer assembly to the core; sealing along two opposed side edges of the integral multilayer assembly; rolling the integral multilayer assembly in a spiral configuration on the core; and bonding the seals by induction heating so as to fluidly seal the integral multilayer assembly along the edges and the central portion and so as to separate the integral multilayer assembly into a first reverse osmosis multilayer assembly and a second reverse osmosis multilayer assembly. In one embodiment, sealing is obtained by disposing an impermeable adhesive along the length of a central portion of the integral multilayer assembly; and disposing an impermeable adhesive along the side edges of the integral multilayer assembly.

The method further comprises enclosing the spirally rolled and bonded integral multilayer assembly in a housing having an inlet for passage of water for a source, a first outlet for passage of purified water from the passage of purified water from the housing and a second outlet for passage of waste water remaining after purification, disposing the first reverse osmosis multilayer assembly within the housing in fluid communication with the inlet for purification of at least a first portion of the water from

the source, and disposing the second reverse osmosis multilayer assembly within the housing in fluid communication with the first reverse osmosis means to receive the first purified portion of water for purification of at least a second portion of the purified water, the second reverse 5 osmosis means also being disposed in fluid communication with the second outlet for passage of waste water through the second outlet.

Alternatively, the method can comprise providing an integral reverse osmosis multilayer assembly having first 10 reverse osmosis membrane layer; first porous mesh layer; second reverse osmosis membrane layer; porous permeate layer; third reverse osmosis membrane layer; second porous permeate layer; fourth reverse osmosis membrane layer; and third porous permeate layer.

15 The present invention is also directed to a device for sterile coupling and decoupling of a drug container to a delivery system, the container having an open end and a puncturable seal adapted for entry into the open end so as to seal the open end comprising a housing configured and 20 dimensioned for receiving and cooperating with the plug so as to provide a fluid tight cooperating engagement when the plug enters the housing; barrier means disposed within the housing and having a portion thereof adapted for sterile penetration 25 of the barrier means by a conduit of the delivery system; an inlet duct and an outlet duct disposed through the housing and disposed between the barrier means and the plug when positioned within the housing. The inlet duct is adapted for fluid coupling to a source of sterilizing fluid, and the outlet duct is adapted for fluid coupling to a reservoir 30 container to receive the sterilizing fluid after passing across the portion of the plug facing the barrier means.

35 The present invention is also directed to a hemoultrafiltration system for treating a patient comprising reverse osmosis device for purifying water from a source and

having input means for coupling to the source of water; first reverse osmosis means being in fluid communication with the input means for purification of at least a first portion of the water from the source; and second reverse osmosis means being in fluid communication with the first reverse osmosis  
5 means to receive the purified first portion of water for further purification of at least a second portion of the water; and means for supplying a predetermined amount of drug; means for mixing the purified second portion of the water with the drug to provide a blood make up solution; and  
10 means for delivering the blood make up solution to the concentrated blood outlet of a hemoultrafilter. The system further comprises means for draining waste water from the reverse osmosis device and also means for draining spent waste solution from the hemoultrafilter. The reverse osmosis  
15 device further comprises chemical means being in fluid communication with the first reverse osmosis means to receive the first purified portion of water and for removal of at least chemical contaminants from the first purified portion of water before passing on to the second reverse osmosis  
20 means. Means for heating the water from the source is provided and is coupled to the input means of the reverse osmosis device so as to heat the water before purification. A high pressure pump is fluidly coupled between the source and the reverse osmosis device so as to provide sufficient  
25 pressure to allow for proper operation of the reverse osmosis device. The system further comprises means for heating the water from the source which is fluidly coupled between the high pressure pump and the source so as to heat the water before purification. The means for heating the water from the source can also be fluidly coupled between the high pressure pump and the reverse osmosis device so as to heat the water before purification. The reverse osmosis device further includes a first outlet for passage of purified water from the second reverse osmosis means and a second outlet for  
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passage of waste water. The reverse osmosis device further comprises a third outlet for passage of waste water. The apparatus first osmosis means is in fluid communication with the third outlet so as to permit passage of waste water through the third outlet. The second reverse osmosis means 5 is in fluid communication with the second outlet for passage of waste water through the second outlet. A heat exchanger means is fluidly coupled to the second and/or third outlet of the reverse osmosis device and is disposed in thermal relationship with the water from the source so as to provide for transfer of heat from the waste water to the water to be heated. Alternatively, the heat exchanger means can be 10 fluidly coupled to the means for draining spent waste solution and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from 15 the solution to the water to be heated.

According to the system, the supplying means comprises a storage container having a coupling end and containing a predetermined drug, and a metering system in fluid communication with the coupling end of the storage 20 container to receive a predetermined amount of drug and is further in fluid communication with the purified second portion of the water after passing through the first outlet. The system further comprises means for sterilizing the coupling end of the storage container when being coupled and decoupled to the metering system. The mixing means is in 25 fluid communication with the first outlet and the metering system so as to receive the purified second portion of the water and the predetermined amount of drug for preparation of a blood make up solution. The mixing means can be an ultrasonic, electromagnetic, electromechanical or a static 30 mixer. Pump means is fluidly coupled between the supplying means and the reverse osmosis device. Pump means can also be fluidly coupled between the mixing means and the hemofilter, and also between the hemofilter and a drain 35

means for receiving the spent waste solution. A computer means provides for predetermined, selective and automatic control of the delivery means, the supplying means, the mixing means and the draining means.

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#### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described in greater detail hereinbelow, with reference to the drawings wherein:

10 FIG. 1 is a schematic view of an automatic peritoneal dialysis system employing an RO device according to the present invention.

15 FIG. 2 is a partial schematic view of the automatic peritoneal dialysis system of FIG. 1 for use with a single lumen catheter.

FIG. 3 is a partial schematic view of the system of FIG. 1 adapted for use with a hemodialyzer.

15 FIG. 4 is a cross sectional view of an RO device according to the present invention.

20 FIG. 5 is a perspective view exposed in part of the RO device of FIG. 4 to illustrate generally the internal components and arrangement.

25 FIG. 6 is a perspective view exposed in part of the RO device of FIG. 4 to illustrate the various fluid flow paths.

FIG. 7 is a cross sectional end view taken along the lines 7-7 of FIG. 4.

30 FIG. 8 is a cross sectional view of an alternative embodiment of the RO device according to the present invention.

FIG. 9 is a perspective view exposed in part of an alternative RO device of FIG. 8 to illustrate generally the internal components and arrangement.

FIG. 10 is a perspective view exposed in part of an alternative RO device of FIG. 8 to illustrate the various fluid flow paths.

FIG. 11 is a cross sectional end view taken along the lines 11-11 of FIG. 8.

5 FIG. 12 is a front view of the metal top portion of cap for sealing the open end of the housing of the RO device of FIGS. 4 and 8.

FIG. 12A is an inside view of the plastic portion of the cap of FIG. 12.

10 FIG. 12B is an inside view of the second pressurized container inside the housing of the RO device according to the present invention.

15 FIG. 13 is a transverse cross sectional view of the RO multilayer assembly prior to winding about the core of the RO device of FIGS. 4 and 8.

FIG. 14 is an exploded cross sectional view of the RO multilayer assembly of FIG. 13.

FIG. 15 is an exploded cross sectional view of the RO membranes of FIG. 14.

20 FIG. 16 is a cross sectional view of still another embodiment of the RO device according to the present invention.

25 FIG. 17 is a transverse cross sectional view of the formation of the RO multilayer assembly of the RO device of FIG. 16.

FIG. 18 is a cross sectional view in the opposite direction of FIG. 17 of the RO multilayer assembly of the RO device of FIG. 16 in an assembled configuration and illustrating the fluid flow paths.

30 FIG. 19 is an exploded cross sectional view of the RO multilayer assembly of FIG. 18.

FIG. 20 is a cross sectional view of yet another alternative embodiment of an RO device according to the present invention wherein the inlet port is at a different end than the outlet ports.

5 FIG. 21 is a cross sectional view of still another alternative embodiment wherein the inlet port is generally transverse to the outlet ports.

FIG. 22 is a cross sectional view of a portion of a heat exchanger according to the present invention.

10 FIG. 22A is an end view along lines 22A-22A of FIG. 22.

FIG. 23 is a side end view of the first layer of the heat exchanger prior to assembly about the core.

15 FIG. 24 is a top view of the first layer of FIG. 23.

FIG. 25 is a side end view of the first and second layers of the heat exchanger prior to assembly about the core.

20 FIG. 26 is top view of the second layer of FIG. 25 with the first layer removed.

FIG. 27 is a schematic view of an alternative embodiment of a purification system employing an RO device according to the present invention for use in an automatic peritoneal dialysis system or other application uses.

25 FIG. 28 is a side view of a restrictor for use in the RO device according to the present invention.

FIG. 28A is a view along lines 28A-28A of FIG. 28.

FIG. 29 is a perspective view of the restrictor of FIG. 27.

30 FIG. 30 is an exploded side view of an alternative embodiment of a restrictor according to the present invention.

FIG. 31 is an end view of the restrictor assembly of FIG. 30.

FIG. 32 is a perspective view of the application of induction heating to at least a portion of the RO multilayer assembly for heating of the adhesive bond during the assembly of the RO multilayer assembly.

5 FIG. 33 is an alternative embodiment of an induction heater for use in the fabrication of the RO multilayer assembly of the RO device according to the present invention.

10 FIG. 34 is a method of sonic welding the cap to the hollow core of the RO device.

15 FIG. 35 is a method of performing a sterile connection.

FIG. 36 is a partial schematic view of the system of FIG. 1 generally adapted for use in hemofiltration.

15 DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the description which follows, any reference to either orientation or direction is intended primarily for the purpose of illustration and is not intended in any way as a limitation of the scope of the present invention.

20 The peritoneal dialysis system (PDS) 10 of Fig. 1 of the present invention is designed to preferably utilize potable water and prepackaged drug mixtures or concentrate to enable a patient to obtain peritoneal dialysis at home and preferably at night. If desired, other sources of water can be utilized as well. For instance, non-potable tap water can be used to produce potable water by the RO device which in turn can be utilized by the peritoneal dialysis system.

25 As shown in FIG. 1, potable water from a source 12 is admitted optionally through prefitter 13 to remove particulates which are greater or equal to about 5 microns in size and through a valve 14 and heat exchanger 16 into a heater 18 and thereafter is passed through a high pressure pump 20 to the reverse osmosis (RO) device 22 according to the present invention. Within the RO device 22, some of the

potable water is purified and exits optionally through a sterilizing filter 23 into a surge container such as a bag 24. The waste water is passed through an on/off clamp 26 to the heat exchanger 16. The heat exchanger 16 transfers at least a portion of the heat from the waste water so as to 5 warm the original potable water before the potable water passes through heater 18. The on/off clamp 28 can regulate the passage of the purified permeate to the surge container 24 and an on/off clamp 30 can alternatively allow for passage of excess permeate to the drain or another collection 10 container for storage through the isolation one-way valve 56.

A conductivity sensor 25 is placed downstream of the RO device 22 to continually or periodically monitor the electrical resistivity of the purified permeate water.

Alternatively, the conductivity sensor may be placed 15 downstream of on/off clamp 30 to periodically monitor the electrical resistivity of the purified permeate.

A pump 32 passes the ultrapure water or permeate from the surge container 24 to mixing bags 34 and 36. Concentrate such as a prepared drug or other desired mixture 20 from sources 38 and 40 passes through metering pumps 42 and 44 that pass a predetermined amount of concentrate into the mixing container 34 and 36 that can mix and measure and alternatively feed to the downstream pump 46. Also, drug sources in addition to sources 38, 40 can be provided, as 25 desired, or only one may be utilized if preferred. In a preferred embodiment, source 38 could include a predetermined dextrose solution of about 65% concentrate. To allow for conductivity monitoring, the dextrose source 38 can be provided with a predetermined amount of electrolytes that can 30 be measured upon coming into contact with conductivity sensor, which will be discussed in more detail below. Similarly, other sources can be provided with electrolyte markers that would allow for conductivity measurement as well. Of course, to the extent that other sources already 35

contain electrolytes, any additional markers are not required but could aid in the measurement process. Conductivity sensors 75 and 77 are placed downstream of mixing bags 34 and 36 respectively so as to continually or periodically monitor the electrical resistivity of the mixed solutions from the mixing bags. Alternatively a conductivity sensor may be placed downstream of clamp 76 and 78 so as to periodically monitor the electrical resistivity of the mixed solutions from the mixing bags. The conductivity sensors may also be used to aid in the formulation of the dialysate.

Advantageously, a heater 45 is used to control the temperature of the dialysate within desired ranges.

By means of the high accuracy pump 46, the dialysate is then admitted through a dual lumen catheter 48 into a patient's peritoneal cavity 50. Discharge from the patient is provided by a downstream high accuracy pump 52 into a discharge measurement container 54 and thereafter, through pump 55 and an isolation one-way valve 56, which serves as a barrier against virus, bacteria and pyrogen, to a drain 58. Alternatively, with the on/off clamp 84 closed and on/off clamp 86 opened, the discharge from the patient passes through the heat exchanger 16 to transfer at least a portion of the heat from the discharge so as to warm the original potable water before the potable water passes through heater 18. The discharge is subsequently drained off through isolation one-way valve 56 to drain 58.

The surge container 24 is optionally supported by hook means 60 which is connected to weight measurement mechanism 64. The discharge measurement container 54 is supported by hook means 62 which is connected to weight measurement mechanism 66. In one preferred embodiment, the weight measurement mechanisms provide electrical signals corresponding to the weight of the contents of the respective

container. These signals are transmitted to a computer control system (not shown in FIG. 1) that is discussed in greater detail below.

As shown in FIG. 1, an outlet through on/off clamp 71 is provided upstream of the mixing containers 34 and 36 for flushing, priming and calibrating. Additional clamps 72 and 74 are provided to close off the downstream flow paths when clamp 71 is opened. In this manner, the permeate or ultrapure water combining with concentrate from sources 38 and 40 can initially be passed through isolation valve 56 to drain until proper operation and priming is obtained.

Thereafter, clamp 71 is closed and clamps 72 and/or 74 are opened according to the desired operation. When clamps 72 and 74 are closed and clamp 71 is left open, the discharge measurement container 54 along with the hook means 62 and weight measurement mechanism 66 can then be used to calibrate the delivery rate of the pumps 32, 42 and 44 individually. Similarly, when clamp 47 is opened and clamp 49 is closed, the discharge measurement container 54 along with the hook means 62 and weight measurement mechanism 66 can be used to calibrate pumps 46 and 80 individually. When both clamps 47 and 49 are closed, calibration of pump 52 can be performed. Other on/off clamps 76 and 78 control the outflow from mixing containers 34 and 36.

The on/off clamp 86 and pump 55 control the flow of the discharge from the discharge measurement container 54 to the heat exchange 16 and isolation one-way valve 56. Alternatively, with clamp 86 closed, the discharge can flow through pump 55 and clamp 84 to the isolation one-way valve 56 to drain 58.

Within the mixing containers 34 and 36, the concentrate and permeate are adequately mixed to provide a dialysate solution suitable for the peritoneal dialysis treatment of the patient 50. The mixing can be performed by known methods which include, for example, ultrasonic,

mechanical, static and also electromechanical modes of mixing. One preferred embodiment of mixing apparatus is of the electromechanical type and is described in greater detail below.

5        Optionally, a container 82 and pump 80 are connected just upstream of clamp 49 to provide a method of administering drugs into the patient 50. Such drugs include but are not limited to insulin, heparin, antibiotics, erythropoietin, and nutritional supplements like calcium, magnesium and amino acids.

10      The dual lumen catheter 48 is of a configuration that is surgically implanted into the patient 50 and extends into the peritoneal cavity by appropriate lumen tubing (not shown) as is well known to those in the medical art. One lumen is coupled to the pump 46 while the other lumen is  
15      coupled to discharge pump 52.

20      In operation, potable water such as from a tap, is passed through valve 14, warmed to the desired temperature by heat exchanger 16 and heater 18 and pumped under pressure through pump 20 into RO device 22. Some of the tap water is  
25      purified and sterilized so as to be free of pyrogens and to have an electrical resistivity of greater than approximately 0.05 megaohms per centimeter, which corresponds to about 25 ppm dissolved solids content, as determined by conductivity sensors. Waste water exits through clamp 26 and goes into the heat exchanger 16. The purified water or permeate is  
30      optionally passed through a sterilizing filter (i.e., .22 micrometer ( $\mu$ m) filter) and then admitted into a surge container 24 where it is optionally measured and stored, as desired, until pumped out by pump 32 into mixing containers 34 and/or 36. Also, concentrate of a prepared drug and treatment mixture, in paste, liquid or solid form is premeasured in source 38 and 40 and advanced by metering device such as pumps 42 and 44 or other delivery techniques or methodologies into the flow path passing with the permeate  
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into the mixing containers 34 and/or 36. After suitable mixing the dialysate solution in mixing containers 34 and/or 36 is pumped into the patient 50 by pump 46 through one lumen of the dual lumen catheter 48. Optionally, drugs may be 5 administered to the patient 50 by pumping the drugs from containers 82 into the line just upstream of the catheter. In a continuous mode of operation, the waste dialysate is pumped from the peritoneal cavity through pump 52 to the drain 58 or alternatively to heat exchanger 16 before being released 10 through drain 58. The PDS system 10 of the present invention can also be operated for intermittent and tidal modes of peritoneal dialysis treatment, as desired. In some modes, the dual lumen catheter 40 can be replaced at points A and B with a single lumen catheter in accordance with known procedures as 15 shown in Fig. 2.

Where the present system is adapted to supply sterile dialysate for use with a hemodialyzer 300, the catheter is replaced at points A and B by fluid connections to a hemodialyzer 300 as shown in Fig. 3. Metering pumps 302 and 20 304 are used to flow the patient's blood into and out of the hemodialyzer 300. Alternatively, the catheter can be replaced at points A and B by fluid connections to a hemoultrafilter 900 as shown in Fig. 36. Metering pumps 902 and 904 are used to flow the patient's blood into and out of the 25 hemoultrafilter 900. A general description of hemofiltration of blood is presented in "Handbook of Dialysis", Little, Brown and Company, Boston/Toronto (1988) at pages 144-45 which are incorporated herein by reference. In the course of 30 hemofiltration treatment, about 25 to 120 liters of blood make up solution will be supplied from point A in Fig. 36 to be combined with the concentrated blood exiting from the hemoultrafilter device 900. Waste solution exits from the hemoultrafilter device at point B.

The flow paths shown in FIG. 1 are provided by tubing well known to medical personnel. However, the tubing or flow paths downstream of the RO device 22 and through to the catheter 48 are maintained preferably in a sterile condition. For this reason, connections or couplings of the tubings and the various components of the PDS system 10 are kept sterile as well. Preferably, these flow paths including the RO device are provided in a modular compartment, as described in greater detail below, so that the patient need only replace the module compartment when necessary to replenish the RO device or the concentrate. The RO device itself is sterilized by radiation. Likewise, the concentrate is sterilized by terminal sterilization or by a sterile filling technique as taught, for example, in U.S. Pat. application 07/510,317, R.J. Kruger, et al. filed 4/17/90 for "Method for Sterilizing and Enclosure with Non-Condensing Hydrogen Peroxide-Containing Gas", which is incorporated herein by reference. Alternatively, a sterile connecting technique described in Fig. 35 may be used for connecting containers 38, 40 and 82 to the system as shown in Fig. 1.

As shown in Fig. 35, a glass bottle container 580 having a rubber septum cap 582 is placed into a receiving holder 586 having a rubber septum seal 588. The receiving holder 586 holds the rubber septum 582 in a fluidly sealed manner and is disposed adjacent to the rubber septum seal 588 so as to leave a space 590. Hydrogen peroxide solution from about 2% to about 50% concentration is then introduced into the space 590 through inlet 592 to sterilize the space 590. When the sterilization is completed the hydrogen peroxide solution may discharge through outlet 594. Subsequent to the sterilization the dual lumen needle 596 or optionally two needles is moved upward puncturing the rubber septum seal 588 and the rubber septum 582 so as to steriley connect the glass bottle container 580 to the system.

Sterile decoupling may be performed by retracting the dual lumen needle 596 below the rubber septum seal 588. The rubber septum 582 can then be decoupled from receiving holder 586 without contaminating dual lumen needle 596.

5 To further maintain sterile conditions, fluid is drained out of the system through an isolation, one-way valve 56 so as to prevent the introduction of virus, bacteria and pyrogen from the drain 58.

10 The above combination of procedures for maintaining sterile conditions lessens or greatly reduces the likelihood of pyrogens and bacteria and viruses entering the flow paths and thereby the peritoneal cavity of patient 50. As a result of the system being able to maintain highly sterile conditions, a final .22  $\mu\text{m}$  sterilizing filter immediately upstream of the catheter is not required before the dialysate 15 is delivered to the patient.

20 The PDS system 10 of the present invention allows not only daytime or acute use but also for nighttime peritoneal dialysis treatment of patients. In this manner, patients can avoid the difficulties and discomfort that occurs with other peritoneal dialysis treatments requiring hospital or clinic visits. It is advantageous to utilize nighttime treatment in order to permit the patient to lead a more normal life during the waking hours. In addition, the 25 method of treatment preferably to be employed with the PDS system of the present invention will require less dialysate to be stored within the peritoneal cavity during the dry period since there will be sufficient dialyzation by the continuous surge and flushing of the dialysate through and from the peritoneal cavity during the wet period.

30 In addition, the PDS system 10 is a gentler treatment system than that which is obtained with the more dramatic hemodialysis. In addition, the psychological factors inherent in hemodialysis treatment are avoided by the 35 present system. Furthermore, the PDS system 10 is a simpler

and less complicated system than is required with hemodialysis. The PDS system 10 thus allows a patient to avoid the dramatic environment facing such a patient in a hospital or clinic for either hemodialysis or conventional peritoneal dialysis treatments.

5       Also, by allowing the peritoneal membrane to be dry for a good portion of the day, problems otherwise present with other treatments can be avoided or minimized. Furthermore, the PDS system 10 by means of the compact and low cost RO device or cartridge which need only be replaced  
10      once every one to six, preferably three days, will help to reduce the cost of treatment within the range of a greater number of patients. Furthermore, the PDS system 10 will allow for shipment of small volume prepackaged drug  
15      concentrates in a paste, liquid or dry state which can then be combined with the ultrapure water prepared directly at the patient's home site by means of the RO device cartridge.

20      In an alternative embodiment of the PDS system 10, the operation will be computer controlled and will only require an on-off button so that entire treatment programs can be implemented from a computer system. Furthermore, diagnostic sensors may be included in order to measure the urea and other metabolites so as to provide for a constant monitoring and desired treatment of the patient. Such a computer system will also permit the patient or care giver to  
25      modify the treatment stages and the volume of treatment fluid as desired. Also, such a computer system will allow the treatment process to be fine tuned to the specific medical needs of the patient. In general, the PDS system 10 provides a custom care treatment as well as an improved quality of  
30      life for the patient.

35      One specific manner in which the PDS system 10 may control peritoneal dialysis is to control the fluid flow rates through pumps 46 and 52. Typically, the total volume introduced into the peritoneum is less than the total volume

drained out of the peritoneum. This volume difference is due to the ultrafiltrate or excess water generated in the body which is drawn into the peritoneum by osmotic pressure and which contributes to the total volume of water draining out. The PDS system 10 may thus set the flow through pump 52 at a greater rate than through pump 46 to compensate for this volume difference.

Another manner of controlling the peritoneal dialysis is to set the maximum fluid pressure in the inlet line near point A to 48 inches of water and to set the outlet line near point B to a maximum of minus 38 inches of water. This effectively prevents the pressure within the peritoneum from exceeding 30 inches of water. Preferably, the pressure within the peritoneum should be less than eight inches of water and most preferably less than 5.5 inches of water. These pressure maximums are chosen so as to minimize the adverse effect of fluid pressure within the peritoneum to cardiac output and vital capacity as disclosed in "Reduction of Vital Capacity Due to Increased Intra-Abdominal Pressure During Peritoneal Dialysis", by L. Gotloib, et al., P.D. Bulletin, Vol. 1, 63-64 (1981), which is incorporated herein by reference.

As shown in FIGS. 4 and 5, the reverse osmosis (RO) cartridge of the present invention has a cylindrical hollow housing 102 forming a chamber 104 within which a hollow mandrel core 106 open at both ends is disposed within the chamber 104 so that the axis of the core 106 is coaxial to the axis of the chamber 104. The core preferably is formed of ABS plastic and can be molded but preferably extruded. The housing is formed of pressure-containing material - steel, fiberglass, Kevlar<sup>™</sup> or aluminum to provide a light yet strong structure.

As shown in Fig. 14, an RO multilayer assembly 108 includes a porous permeate mesh or carrier layer 110, a first RO membrane layer 112, a feed water mesh or carrier layer 114

and second RO membrane layer 116. The RO membranes 112 and 116 are each formed of a composite, non-porous, semipermeable membrane 200, an ultrafiltration membrane 202 and a polyamide cloth 204 as shown in Fig. 15. RO membranes of this specific structure can be obtained from FilmTec Corporation, a division of Dow Chemicals, with a membrane designation of BW30. Such an RO membrane is also disclosed in U.S. Patent 4,277,344 of J.E. Cadotte, assigned to FilmTec Corporation and issued July 7, 1981 which is incorporated herein by reference. The RO multilayer assembly 108 is fixed to and rolled about the surface of the core 106 as shown in FIG. 7. An impermeable glue seal 118 is provided at about the middle of the RO multilayer assembly 108 prior to rolling and is disposed approximately perpendicular to the core 106 so that the glue seal 118 separates the RO multilayer assembly 108 into two stages 120 and 122 when the RO multilayer assembly 108 is spirally wound about the core 106. The side edges of the RO multilayer assembly 108 are also sealed by glue bonds 124 and 126. Thus the first and second stage 120, 122 are fluidly separated from one another. Preferably, the glue seal is made of a transparent glue capable of water vapor curing available under a trade name of H. B. Fuller Product #UR-0330. In order to provide visibility, the glue can be mixed with a coloring agent. Coloring agents include carbon black, fiber glass, mica, metallic particles, calcium carbonate and titanium dioxide at .25-3% by weight of glue preferably less than 1%. Particle size for the coloring agent range from .1 to 5  $\mu\text{m}$ , preferably 1-2  $\mu\text{m}$ . If carbon black is used, the glue becomes gray in color and also results in an improved wettability and better bonding.

The housing 102 has a base 128 which is dimpled inwardly toward the interior of chamber 104 as shown in FIG. 4. The housing 102 is open at its other end which is sealed by a cap assembly 130 that is formed of two pieces. An integral cap member 132 made of the same plastic material

from which the core 106 is fabricated and an annular steel cap plate 136 which at its inner end seals about a periphery of cap member 132 and at its outer end seals in a formed manner with rolled edge 138 of the housing 102. As shown in FIG. 12, the annular steel cap plate 136 provides openings 5 140a, 142a and 144a for an inlet tube 140 of cap 132 which is coupled by suitable tubing (not shown) to the high pressure water from pump 20 as shown in FIG. 1; the drain outlet tube 142 and optionally 147; and a permeate or purified water outlet 144 as shown in FIGS. 9, 12A and 5. The radial ribs 10 of the annular steel cap plates 136 are optional and are not required. The core 106 contains a hollow space 146 to receive therein activated carbon 145 which is held in place between depth filters 148 adjacent the base 128 and 150 which is adjacent the cap 132.

15 As shown in FIGS. 7 and 14, a first RO multilayer subassembly 210 at one end 212 can be affixed in a longitudinal slot 214 from which the multilayer subassembly 210 is spirally wrapped around the core 106. This first multilayer subassembly comprises a porous permeate carrier 20 layer 110 and a first RO membrane layer 112. A second RO multilayer subassembly 216 can be affixed in a second longitudinal slot 218 and is also spirally wrapped around in the same direction as the aforementioned RO multilayer subassembly 210. This second RO multilayer assembly 216 25 comprises a feed water mesh layer 114 and a second RO membrane layer 116. At the other end of the membrane multilayer subassembly 210, the edge is kept open to allow tap water under pressure to enter. The dotted circle 220 indicates the actual radius of the complete RO multilayer assembly when wound onto the core 106.

30 35 The RO device, as shown in FIG. 4, also includes a pressurized container 166 which is generally cylindrical having a closed end 168 resting adjacent the dimpled end of base 128 and secured by a hot melt glue bead 169. The other

end of pressurized container 166 is open and is dimensioned so as to receive the rolled RO second stage 122 therein. The core 106 is sonically welded to the inner base wall of the pressurized container 166. An O-ring 170 provides additional sealing to facilitate the potting of glue seal 119 which is adjacent the glue seal 118 and the inner wall of pressurized container 166. If desired, additional O-rings can be provided as well as other sealing means according to methods known to those of the sealing art. For example, an adhesive seal can be provided next to the O-ring above the glue seal 118 and below the O-ring after assembly within the pressurized container 166. In this manner, the second stage 122 is fluidly sealed from the first stage 120. The depth filter 148 is pressed in contacting relationship with a bead 172 which helps to seat the core 106 within the pressurized container 166. However, the passageways 125 are kept spaced from the base of pressurized container 166, as shown in FIG. 4 and 12B so that the fluid communication of those passageways is maintained with a chamber 174 formed therein.

As shown in FIG. 7, the core 106 has additional passageways 222 which are simply provided to lighten the weight of the core 106 and do not provide any operational function in the RO device.

In a preferred configuration, a small RO device may have an effective RO membrane surface for each of the stages 120 and 122 of about .5 square feet to about 1.5 square feet. A large RO device may require substantially more surface area ranging up to industrial sizes of hundreds of square feet. The rejection rate of the first stage is at least 90%. The rejection rate of the second stage is at least 60%. The overall performance of both stages in combination will be at least 96% rejection. The operating pressures across the membranes of the first and second stages are preferably about 125 psi each. The dimension of the housing 102 of the RO device is preferably about 7 inches in length, 2.3 inches in

diameter. The dimension of the hollow core 106 of the RO device is preferably about 6.3 inches in length and about 1.25 inches in diameter.

In operation, the various fluid paths of the RO device are illustrated in FIG. 6, which shows that pressurized tap water enters through inlet 140 and thereafter through passageway 152. Upon entering the first stage 120, the pressurized water passes through the RO multilayer assembly. The first portion of purified water from the tap water is passed into the longitudinal passageway 123 and toward the cap member 132 and thereafter is directed by guide 124 through depth filter 150 (See Fig. 4) into the hollow space 146 containing activated carbon 145. Upon passing through the length of the hollow space 146, the now chemically purified water passes through depth filter 148 (See Fig. 4) and then through guide 125 to the chamber 104 from which the chemically purified water enters in the RO multilayer assembly of the second stage 122. Upon further filtration within second stage 122, the finally purified water passes into passageway 154 and exits through permeate outlet 144. The drain water from the first stage 120 enters into passageway 156 and then through restrictor 224 as indicated in Fig. 7 and described below in Figs. 28-31. The second stage 122 enters into a passageway 158 and then through restrictor 226 as indicated in Fig. 7 and described below in Fig. 28-31. The fluid from restrictors 224 and 226 combine within guide 143 and subsequently drains through outlet 142. Alternatively, the fluid from the first stage restrictor 224 can drain directly through optional outlet 147 and the fluid from the second stage restrictor 226 can drain directly through outlet 142 as shown in Fig. 6.

An alternative embodiment of the RO device according to the present invention is illustrated in FIGS. 8-11, wherein structural features common to the embodiment shown in Fig. 4 are depicted by the like number. The main

difference in construction from that shown in Fig. 4 is that the first stage 122 is away from the inlet 140 and is fitted against the inner wall of the pressurized container 166 and the second stage 120 is closest to the inlet 140.

In operation, the various fluid paths of the RO device are illustrated in FIG. 10, which shows that pressurized tap water enters through inlet 140 and thereafter through passageway 123 within core 106. Upon approaching the base 128 of pressurized container 106 the pressurized water enters through guide 125 into passage chamber 174 and thereafter into the RO multilayer assembly of the first stage 122. The first portion of purified water from the tap water is passed into the longitudinal passageway 146 and back toward the base 128 which thereupon admits through guide 126 the first purified portion into the hollow space 146 containing activated carbon 145 within the hollow core 106. Upon passing through the length of the hollow core 106, the now chemically purified water enters the chamber 104 through guide 127 from which the chemically purified water enters into the RO multilayer assembly of the second stage 120. Upon further filtration within second stage 120, the finally purified water passes into passageway 156 and exits through outlet 144. The drain water from the first stage 122 enters passageway 158 and then through a restrictor as described below in Fig. 28-31. The drain water from the second stage 120 enters passageway 154 and then through another restrictor. The fluid from both restrictors combine within guide 143 and subsequently drains through outlet 142. Alternatively, the fluid from the first stage restrictor can drain directly through another outlet (not shown) and the fluid from the second stage restrictor can drain directly through outlet 143.

In both of the above embodiments shown in Figs. 4 and 8, the RO multilayer assembly which is wound about the hollow core 106 is attached onto the core 106 by means of two

slots 214 and 218 as shown in Figs. 7 and 13. Preferably, one or more of the ends of the RO multilayer assembly is attached to the hollow core 106 by means of an adhesive strip 228 without placing the end into any slot as shown in Fig. 11. The RO multilayer assembly is thereby divided into two parts in its attachment to the core 106. Fig. 14 schematically illustrates the various layers of the RO multilayer assembly. As shown in Fig. 13, the first part which is attached to slot 218 comprises a porous mesh layer 114 and a second RO membrane layer 116. The second part which is attached to slot 214 comprises a porous permeate layer 110 and a first RO membrane layer 112. In operation, the unpermeated tap water is drained out from the porous mesh layer 114 and through passageways 158 and 156 within core 106 to drain outlet 142. The purified water which has permeated through the RO membrane layer 112 and 116 passes from the porous permeate layer 110 through passageways 123 and 154 within the core 106 and to permeate outlet 144.

When the multilayer is wound about the core, the RO multilayer assembly is configured as shown in FIG. 14. The first and second RO membrane layers 112 and 116 are faced in opposite directions from each other because of the structure of the RO membrane layer which is shown in FIG. 15. Adhesive beads 206 are disposed against the porous mesh layer 114 and the porous permeate layer 110 as shown to form the RO multilayer assembly. The RO membrane layers 112 and 116 comprise a nonporous, semipermeable membrane 200 and an ultrafiltration membrane 202 and a polyamide cloth 204 as shown in Fig. 15. The RO membrane layers 112 and 116 in Fig. 14 illustrate the relative position of the nonporous, semipermeable membrane 200 with respect to the other layers. Specifically, the nonporous, semipermeable membrane layers of the RO membrane layers 112 and 116 are adjacent to the porous mesh layer 114.

Another alternative embodiment of the RO device according to the present invention is illustrated in FIG. 16, wherein structural features common to the embodiment shown in FIG. 4 are depicted by like number. As shown in FIG. 16, the RO device 400 has a central core 106 which is positioned 5 within an end base cap 402 and secured to adjacent base 128 of housing 102 by hot melt glue bead 169. As shown in Fig. 17, four RO multilayer subassemblies 316, 318, 320 and 322, are affixed in longitudinal slots 324, 326, 328 and 330, respectively, in core 106. Alternatively, the ends of the 10 subassemblies may be attached to the core by adhesive beads. RO multilayer subassembly 316 is formed of a nonporous, semipermeable membrane layer 302 and a porous permeate layer 304. The RO multilayer subassembly 318 is similarly formed of a nonporous semipermeable membrane layer 306 and a porous 15 permeate layer 308. Likewise, the RO multilayer subassembly 320 is similarly formed of a nonporous semipermeable membrane layer 310 and a porous permeate layer 312. The RO multilayer subassembly 322 is formed of a nonporous semipermeable membrane layer 314 and a porous mesh layer 300. Unpermeated 20 tap water exits through passageway 158 and drain outlet 142 and sterilized water exits through passageway 123 and permeate outlet 144. As shown in FIG. 18 which is taken in the opposite direction of FIG. 17, the RO membranes 302, 306, 310 and 314 are spirally wound around the core 106 as well as 25 each other. Alternatively, FIG. 18 represents an RO configuration in which the RO membranes, if desired, can be rolled about core 106 in the opposite direction to that shown in FIG. 17. Interleafed between the RO membranes are the porous mesh layer 300 and the porous permeate layers 304, 308 30 and 312. When the static pressure within the porous mesh layer 300 is TP, the static pressure within the porous permeate layers 304 and 312 is 1/2 TP and the static pressure within the porous permeate layer 308 is about .05 TP. The various flow paths are shown in FIG. 18 as well. In

operation, the alternative embodiment of the RO device of FIG. 16-19 is substantially the same as that described with reference to the RO device illustrated in FIGS. 4 and 8. However, the alternative RO device of FIG. 18 passes the water from the high pressurized source through the two RO 5 stages which are formed of the four RO multilayer subassembly of FIG. 17 before passing through the activated carbon 145 contained in the hollow space 146 within core 106 between depth filters 148 and 150. An exploded cross-sectional view of the RO multilayer assembly of FIG. 18 is shown in FIG. 19. 10 Adhesive beads 206 are disposed against the layers as shown to form the RO multilayer assembly.

The activated carbon serves to remove chloramine as well as dissolved gases from the tap water. In the event that the water supplied to the RO device is already free of 15 chloramines, then there is no need to chemically treat the water. In addition, chemical treatments can be utilized for removal of other chemical species as well. Both the semi-permeable membranes in the RO device of FIG. 4 and the alternative embodiments of FIGS. 8 and 16 are preferably 20 formed of polyamide. However, other semi-permeable membrane layers can be utilized as well.

In both embodiments of the RO device as illustrated and described herein, the RO membranes are formed in a spiral configuration so as to maximize the velocity of tap water 25 across the membrane and to minimize the concentration polarization at the membrane surfaces within as small and compact a housing as possible. This avoids the need to provide for extensive lengths of housing to enclose RO membranes as found in typical applications.

30 Yet another alternative embodiment of the RO device according to the present invention is illustrated in FIG. 20. The RO device 702 includes a generally cylindrical housing 704 having an end cap 706 in which is disposed centrally an inlet port 708 that is fluidly coupled to the source of water 35

to be purified. The other end has a seal cap 710 that is screwed on by threads which engage cooperating threads 712 on the adjacent end portion of housing 704. The seal cap 710 has a waste outlet 714 and a permeate outlet 716. Positioned internally within the housing 704 is a core 701 that is generally cylindrical and is formed of three longitudinal passageways as shown in FIG. 20A. Two of the passageways 720 and 722 are of like shape and together form half of the core 701. The remaining passageway 724 includes activated charcoal for the same purposes as discussed above in connection with the prior embodiments. Passageway 720 is coupled through outlet 714 for passage of waste water. The other like passageway 722 provides for passage of permeate and is coupled to the outlet 716 in seal cap 710. A first RO stage 726 is positioned within chamber 728 formed within housing 704. The second stage 729 is positioned within housing 704 in chamber 730 adjacent seal cap 710. The first and second stages are connected through a restrictor 705. The restrictor 705 is designed to adjust the backpressure within the first and second stages 726 and 729 so as to provide the desired water flow rate across the membranes. The first and second RO stage's 726 and 729 are separated by a core support carrier 732 which is snugly fit within housing 704. The support carrier 732 has a U-shaped channel 734 that extends along the periphery of carrier 732 to receive an O-ring 736 as shown in FIG. 20. In operation, water enters through port 708 and into chamber 728 wherein it enters into the first RO stage 726. After filtration, the filtered portion of the water passes through radial openings 741 in core 701 into passageway 724. Upon passing through the activated charcoal 718 within passageway 724, the partially filtered water passes through radial opening 740 in core 701 into chamber 730 and from there into the second RO stage as shown in FIG. 20. Upon further filtration, the permeate passes out through outlet 716. The waste water from the

first stage passes through radial openings 742 into the return passageway 720 and from the second stage through radial opening 744 also into the waste passageway 720 and finally out the waste outlet 714.

5 In yet another alternative embodiment of the RO device according to the present invention as shown in FIG. 21, the RO device 802 includes a cylindrical housing 804 that includes a first RO stage 806 and a second RO stage 808 which are wrapped around a central core 810. The central core 810 has an inlet port 812 through which water passes into an  
10 interior chamber 814 and thereafter through openings 816 into the chamber 818 in which the first stage 806 is positioned. Upon passing through the first stage 806, the filtered water passes through radial opening 820 in core 810 and thereafter through radial opening 822 into a central portion containing  
15 activated charcoal 823. Upon passing through the charcoal 823, the purified water passes out through radial opening 824 into chamber 826 and through radial opening 828 in core 810 through antechamber 830 and therefrom through opening 832 into chamber 834 in which the second RO stage 808 is  
20 positioned. Upon passage through the second RO stage, the permeate exits through radial opening 836 and out through port 838. The waste water from the first RO stage exits through drain port 840 while the waste water from the second RO stage 808 passes through the drain port 842.  
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In order to provide for proper water flow across the RO multilayer assembly 108, the cylindrical passageway tubes in core 810 are designed in accordance with the Bernoulli equation so that their diameter and length are calculated to produce a static pressure drop across both RO multilayer assemblies 108 of the first stage 806 and second stage 808. The pressure drop produces the desired water flow rate across the membranes. For example, the flow across the second membrane is less than across the first. Static pressure across the first membrane is twice that across the  
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second. This yields a different geometry for the second restrictor. Balancing the spiral resistance with the cylindrical resistance is the key to the proper functioning of the RO Device.

- FIGS. 28 and 29 illustrate a linear restrictor 5 having a barrel 522 and a needle 520 of proper internal diameter and path length to produce the required static pressure drop across both RO multilayer assemblies. FIGS. 30 and 31 illustrate a helical restrictor which serves the same function. The advantage of the helical restrictor 524 is 10 that the pathlength along the restrictor 524 within sleeve 526 can be manually adjusted by screwing the restrictor 524 further into or out of the sleeve 526 by way of a slot 528. The dimension of the helical restrictor 524 is preferably about 1 inch in length, 0.150 inch in diameter with about 16 15 threads per inch and a thread width of .020 inch. The effective path length of such a helical restrictor 524 is therefore about 5.938 inches. The restrictors are disposed within the passageways which fluidly connects the drains of RO multilayer assemblies of the first and second stage. 20 Alternatively, the restrictor may be placed at the outlet drain of stage one and the outlet drain port of the device.

In the operation of the present peritoneal dialysis system (PDS) 10 of the present invention, the potable water can be heated to about 40°C before passing through the RO 25 device 22 as shown in FIG. 1. The higher temperature increases the efficiency of the reverse osmosis process. Specifically about 600 ml/min of potable water can be heated from about 20°C to about 70°C, preferably up to 40°C. In 30 order to decrease the heating demand on heater 18, the heat exchanger 16 transfers heat from the waste water from RO device 22 and patient 50 to the potable water before the potable water passes through heater 18.

The configuration of the heat exchanger 16 is similar to that of the RO device 22 but only requires thin non-permeable membrane multilayer assemblies with porous spacers spirally wound about a hollow core 602 as shown in FIG. 22. Specifically, the heat exchanger 16 contains a 5 first multilayer assembly 604 as shown in FIG. 23 which includes a first porous spacing layer 606 and a non-permeable membrane layer 608. Adhesive beads 610, 612 and 614, preferably of RTV silicon, are applied along the side edges as shown in FIG. 24. A partial adhesive bead 616 is applied 10 to the free end along a portion thereof. A second multilayer assembly 618 shown in FIG. 25 includes a second porous spacing layer 620 and a non-permeable membrane layer 622 that are disposed on the first multilayer assembly 604 such that the first and second porous spacing layers 606 and 620 are 15 interleaved between the two non-permeable membrane layers 608 and 622. Adhesive beads 624, 626 and 628, also preferably of RTV silicon, are applied along the side edges of multilayer assembly 618 as shown in FIG. 26. A partial adhesive bead 630, oppositely disposed to partial adhesive bead 616 in FIG. 20, 24, is applied to the remaining free end of multilayer assembly 618 along a portion thereof.

As shown in FIG. 22, the first and second multilayer assemblies 604 and 618 are wrapped about core 602, preferably made of ABS plastic, and are imbedded within the 25 pressurized container 632 which is similar to container 166 in the RO device of FIG. 4. The end cap 634 seals the heat exchanger unit 16 within a housing (not shown). An O-ring 636 helps to seal the unit 16 within the pressurized container 632. The RTV silicon sealant is shown generally in the assembled form in FIG. 22 at 638. The hot waste water 30 enters through part 640 and cold discharge water exits through port 642 after passing through longitudinal passageway 644. Radial holes 646 in the core 602 admit the spent or cold waste water from between the membrane 35

multilayer assemblies into the passageway 644. Cold potable water enters through port 647. Hot potable water which has received heat transferred from the hot waste water between the membrane multilayer assemblies passes through port 648 in cap 634 after exiting through radial holes 650 in core 602.

5 In operation, hot waste water passes through the first porous spacing layer while tap water passes through the second porous spacing layer. The transfer of heat from the hot waste water to the potable water occurs across the non-permeable membrane layers as the waste and the potable water  
10 flow spirally in a countercurrent or concurrent flow path. The porous spacing layer is preferably polypropylene mesh. The non-permeable membrane layer is preferably a polyester film such as Melinex® or a foil, preferably metallic.

15 Heat transfer efficiency of the heat exchanger 16 is dependent on the membrane material used, the water flow path width, the path length as well as the amount of area available for heat transfer. Consideration of heat transfer efficiency, however, must be balanced with the unfavorable pressure drop through the heat exchanger 16. A preferred  
20 configuration has a heat transfer area of about 300 sq. inches and a pressure drop of about 4 psi at 600 ml/min flow rate.

25 A more general illustration of the use of the RO device is presented in FIG. 27 which illustrates a source of fluid or water 500 which is passed on to a RO device 502. Here again, the waste fluid is passed on to a drain 504 while the purified fluid is passed on to a concentration, mix, store and/or control system 506. Storage can be provided in suitable bags which thereafter can be utilized when desired  
30 for the patient 508 or other end uses 510. If denied, a portion of the purified fluid after use can be returned to the source along fluid path 512. Similarly, some or all of

the waste from the RO device 502 can also be returned to the source and thereafter passed on for purification within the RO device 502.

According to the preferred design, the RO cartridge may be used for three to six days during a weekly treatment and thereafter is discarded. Discarding the cartridge is necessary because of carbon contamination build-up and to avoid a sterility breach. For this reason, there is no need to sterilize while in use the RO membranes so as to remove any contaminants whether chemical or particulate as is required with present systems. In order to provide an RO cartridge suitable for home use, the RO cartridge is designed for optimization of compactness and space as well as performance so as to minimize the cost. This will enable the patient to obtain home treatment without the need to stock a large quantity of sterile water and also further avoids the need to provide for multiple hook-ups as is required in the case of CAPD treatment. Discussion of the concerns and problems relating to connection to multiple water bags is presented in an Optum® brochure entitled "The Hands-Free Exchange For Your CAPD Patients" and U.S. Patent No. 4,840,621 which are incorporated herein by reference.

By means of the use of a dual RO stage system, less expensive RO membrane multilayer assemblies can be utilized so as to still obtain preferably at least a 96% rejection rate. Moreover, the dual RO multilayer assemblies provide a redundancy which is medically desired in the event that one membrane fails. The drastic medical consequences of introducing pyrogen, virus or bacteria in the peritoneal cavity are thus avoided by the present RO device.

The RO device and system of the present invention accordingly overcome the problems of known filtration devices for use in peritoneal dialysis and provide sterile water solutions suitable for peritoneal dialysis and other uses as well and which can easily maintain the desired sterile

conditions. Because of the modular design of the present system, the reverse osmosis device and other system components which are in contact with the water can be periodically disposed of and replaced by new sterile components. The need to have a complicated method of sterilization implemented by the user is therefore avoided.

FIG. 32 illustrates one efficient manner of producing the RO device of the present invention. Specifically, electromagnetically activatable adhesive beads are applied onto the porous mesh layer and the porous permeate carrier layer along the edge and the middle of the multilayer assembly as shown. The manner in which the adhesive bead is applied can be by a roller coating method in which the adhesive is heated in a pot and picked up by a transfer roller (not shown). The transfer roller then prints the adhesive strips 206 onto the porous mesh layer or the porous permeate carrier layer (see Figs. 14 and 19) in a continuous manner as the layers move across the transfer roller. The layers are then combined and rolled onto a hollow core 106. Simultaneous to the rolling of the layers to form the multilayer assembly, the adhesive strips 206 are heated by the induction coils 528. The softened adhesive strips 206 then bond the RO multilayer assembly together as the adhesive cools within the wound layers.

A representative example of such an electromagnetically activatable adhesive may be obtained from Emabond Systems of Ashland Chemical Company, a division of Ashland Oil, Inc. and is taught in U.S. Pat. 3,620,875, issued November 16, 1971 which is incorporated herein by reference.

FIG. 33 illustrates another manner of producing the RO device of the present invention. The adhesive bead 200 has already been applied to the mesh and permeate layers of the RO multilayer assembly. The assembly 108 is subsequently wound about the hollow core 106 and then inserted into a

flexible silicone bladder 530 and attached to cap 532 by ring 534. The wound assembly is then evacuated by vacuum 536 to thereby ensure close contact between the layers of the assembly and the core 106. Induction heating is then applied by coils 538 while the assembly is in the evacuated state so as to bond the layers together. The vacuum in bladder 530 is released by filtered air from 540 after cooling of the adhesive bead has occurred.

Fig. 34 illustrates a method of attaching the integral cap member 132 of the RO device to the hollow core 106 by sonic welding. The ultrasonic vibration of the sonic horn 550 is transmitted through energy transmission guides 552 to energy directors 554 so as to focus the vibration energy to the point of contact with the hollow core 106. Additionally, another sonic horn 556 is used to sonically weld the inner base wall of the pressurized container 166 to the other end of the hollow core 106 through similar energy transmission guides 558 and energy directors 560. Alternatively, the energy directors may be placed on the hollow core 106. Such directional welding can be accomplished at 20 and 40 kHz frequencies. Figs 12A and 12B illustrate the energy directors 554 and 560 respectively in a ridge design so as to seal the passageways of the hollow core to the integral cap member 132 and inner base wall of the pressurized container 166 as shown in FIG. 4. The pattern shown in Fig. 12A and B allows for the sealing of the passageways of the core to the guides of the cap so as to provide fluid passageway inner connections.

The ridge design of the integral cap member 132 shown in Fig. 12A is adapted to provide the RO device of Fig. 6 with the guide 124 connecting passageway 123 and hollow space 146; guide 143 connecting passageways 156 and 158 to waste drain outlet 142; the connection between inlet hole 140 and passageway 152; and the connection between permeate outlet hole 144 and passageway 154.

The ridge design of the inner base wall of the pressurized container 166 shown in Fig. 12B is adapted to the RO device of Fig. 6 so as to seal the ends of the passageways of the core 106. Guide 125 connects the hollow space 146 of the core 106 to the chamber 104 which allows the chemically purified water to enter from the hollow space 146 to the RO multilayer assembly of the second stage 122.

The present invention has been described in detail with particular emphasis on the preferred embodiments thereof. However, it should be understood that variations and modifications may occur to those skilled in the art to which the invention pertains.

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We claim:

1. Apparatus for purifying fluid from a source comprising:

5 a. first reverse osmosis means adapted for fluid communication with the source for purification of at least a portion of the fluid from the source; and

b. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive at least some of the purified portion of fluid for further purification of at least a further portion 10 of the fluid.

15 2. The apparatus according to claim 1 wherein said first reverse osmosis means comprises at least a first reverse osmosis multilayer assembly spirally rolled about a first axis so as to provide a generally spiral flow path of the fluid from the source.

20 3. The apparatus according to claim 2 wherein said second reverse osmosis means comprises at least a second reverse osmosis multilayer assembly spirally rolled about a second axis so as to provide a generally spiral flow path for at least some of the purified portion of fluid from the first reverse osmosis means.

25 4. The apparatus according to claim 3 wherein said first and said second reverse osmosis multilayer assemblies are formed integrally and said first axis and said second axis are colinear.

30 5. The apparatus according to claim 4 further comprising means for fluidly separating said integral multilayer assembly when rolled about its axis into said first and said second reverse osmosis multilayer assemblies.

6. The apparatus according to claim 5 wherein said separator means is an impermeable adhesive.

5 7. The apparatus according to claim 1 wherein said first reverse osmosis means is disposed in an interleaved configuration with said second reverse osmosis means.

10 8. The apparatus according to claim 7 wherein said first reverse osmosis means comprises at least a first reverse osmosis multilayer assembly and said second reverse osmosis means comprises at least a second reverse osmosis multilayer assembly.

15 9. The apparatus according to claim 8 wherein said first and said second reverse osmosis multilayer assemblies are spirally rolled about a common axis.

10. Method for purifying fluid from a source comprising:

20 a. passing fluid from the source through a first reverse osmosis means being in fluid communication with the source so as to purify at least a portion of the fluid from the source; and

25 b. passing the purified first portion of fluid through a second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive at least some of the purified portion of fluid for further purification of at least a further portion of the fluid.

30 11. Apparatus for purifying water from a source comprising:

35 a. first reverse osmosis means adapted for fluid communication with the source for purification of at least a first portion of the water from the source; and

b. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water.

5       12. The apparatus according to claim 11 wherein said first reverse osmosis means comprises a first reverse osmosis multilayer assembly spirally rolled about a first axis so as to provide a generally spiral flow path of the water from the source.

10      13. The apparatus according to claim 12 wherein said second reverse osmosis means comprises a second reverse osmosis multilayer assembly spirally rolled about a second axis so as to provide a generally spiral flow path of the 15 purified first portion of water from the first reverse osmosis means.

20      14. The apparatus according to claim 13 wherein said first and said second reverse osmosis multilayer assemblies are formed of an integral multilayer assembly and said first axis and said second axis are colinear.

25      15. The apparatus according to claim 14 further comprising means disposed on a surface of said integral multilayer assembly so as to fluidly separate said integral multilayer assembly when rolled about its axis into said first and said second reverse osmosis multilayer assemblies.

30      16. The apparatus according to claim 15 wherein said separator means is an impermeable adhesive disposed at least along the length of a central portion, a side end and side edges of said integral multilayer assembly.

17. The apparatus according to claim 16 wherein said integral multilayer assembly comprises:

- a. first reverse osmosis membrane layer;
- b. porous mesh layer;
- c. second reverse osmosis membrane layer; and
- d. porous permeate layer.

5           18. The apparatus according to claim 17 further comprising a container enclosing said first reverse osmosis multilayer assembly.

10           19. The apparatus according to claim 17 further comprising a container enclosing said second reverse osmosis multilayer assembly.

15           20. The apparatus according to claim 11 wherein said first reverse osmosis means is disposed in an interleaved configuration with said second reverse osmosis means.

20           21. The apparatus according to claim 20 wherein said first reverse osmosis means comprises at least a first reverse osmosis multilayer assembly and said second reverse osmosis means comprises at least a second reverse osmosis multilayer assembly.

25           22. The apparatus according to claim 21 wherein said first and said second reverse osmosis multilayer assemblies are spirally rolled about a common axis.

30           23. The apparatus according to claim 22 wherein said first reverse osmosis multilayer assembly comprises:

- a. first reverse osmosis membrane layer;
- b. porous mesh layer;
- c. second reverse osmosis membrane layer; and
- d. first porous permeate layer.

24. The apparatus according to claim 23 wherein said second reverse osmosis multilayer assembly comprises:

- a. third reverse osmosis membrane layer;
- b. second porous permeate layer;
- c. fourth reverse osmosis membrane layer; and
- d. third porous permeate layer.

5            25. The apparatus according to claim 22 further comprising a container enclosing said first and said second reverse osmosis multilayer assemblies.

10

10            26. Method for purifying water from a source comprising:

- 15            a. passing water from the source through a first reverse osmosis means being in fluid communication with the source so as to purify at least a first portion of the water from the source; and
- 15            b. passing the purified first portion of water through a second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of fluid for further purification of at least a second portion of the water.

20            27. Apparatus for purifying water from a source comprising:

- 25            a. housing having an inlet for passage of water from the source, a first outlet for passage of purified water from the housing and a second outlet for passage of waste water remaining after purification;
- 30            b. first reverse osmosis means disposed within said housing and being in fluid communication with said inlet for purification of at least a first portion of the water from the source, said first reverse osmosis

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means also being in fluid communication with said second outlet for passage of waste water through said second outlet;

5           c. chemical means being in fluid communication with said first reverse osmosis means to receive said first purified portion of water and for removal of at least chemical contaminants from said first purified portion of water; and

10           d. second reverse osmosis means being in fluid communication with said chemical means to receive the chemically purified water for purification of at least a second portion of the chemically purified water, said second reverse osmosis means also being in fluid communication with said first outlet so as to permit passage of said second portion of purified water through  
15           the first outlet.

28. The apparatus according to claim 27 wherein said housing further comprises a third outlet for passage of waste water remaining after purification.

20           29. The apparatus according to claim 28 wherein said first reverse osmosis means is in fluid communication with said third outlet so as to permit passage of waste water through said third outlet.

25           30. The apparatus according to claim 27 wherein said second reverse osmosis means is in fluid communication with said second outlet so as to permit passage of waste water through said second outlet.

30

35

31. The apparatus according to claim 30 wherein said first reverse osmosis means comprises a first reverse osmosis multilayer assembly spirally rolled about a first axis so as to provide a generally spiral flow path of the fluid from the source.

5

32. The apparatus according to claim 31 wherein said second reverse osmosis means comprises a second reverse osmosis multilayer assembly spirally rolled about a second axis so as to provide a generally spiral flow path of the chemically purified water from said chemical means.

10

33. The apparatus according to claim 32 wherein said first and said second reverse osmosis multilayer assemblies are formed of an integral generally rectangular multilayer assembly and said first axis and said second axis are colinear.

15

34. The apparatus according to claim 33 further comprising means for fluidly separating said multilayer assembly when rolled about its axis into said first and said second reverse osmosis multilayer assemblies.

20

35. The apparatus according to claim 34 wherein said separator means is an impermeable adhesive disposed along a central portion of said integral multilayer assembly.

25

30

36. The apparatus according to claim 35 wherein said separator means further includes an impermeable adhesive disposed along the side edges of said integral multilayer assembly.

35

37. The apparatus according to claim 34 wherein said separator means is a weld disposed along a central portion of said integral multilayer assembly.

38. The apparatus according to claim 33 wherein said integral multilayer assembly comprises:

- a. first reverse osmosis membrane layer;
- b. porous mesh layer;
- c. second reverse osmosis membrane layer; and
- d. porous permeate layer.

5           39. The apparatus according to claim 38 wherein said first and said second reverse osmosis membrane layers each comprises:

- 10
  - a. nonporous semi-permeable membrane layer;
  - b. porous ultrafiltration layer; and
  - c. porous support layer.

15           40. The apparatus according to claim 39 wherein said semi-permeable membrane layer is formed generally of a solid nonporous continuous thin polymeric composition.

20           41. The apparatus according to claim 39 wherein said porous support layer is formed generally of polyamide.

42. The apparatus according to claim 41 wherein said polyamide is of a woven configuration.

25           43. The apparatus according to claim 42 wherein said polyamide is of a non-woven configuration.

30           44. The apparatus according to claim 38 wherein said housing includes an elongated hollow cylindrical container having a base and an open end.

45. The apparatus according to claim 44 wherein said housing includes a cap configured and dimensioned to fluidly seal said open end and including an inlet passageway

for admitting water from the source, a first outlet passageway for purified water and a second outlet passageway for waste water.

5        46. The apparatus according to claim 45 wherein said cap further comprises a third outlet passageway for passage of waste water.

10      47. The apparatus according to claim 46 wherein said first reverse osmosis multilayer assembly is in fluid communication with said third outlet passageway for passage of waste water from said first reverse osmosis multilayer assembly and said second reverse osmosis multilayer assembly is in fluid communication with said second outlet passageway for passage of waste water from said second reverse osmosis multilayer assembly.

15      48. The apparatus according to claim 45 wherein said second reverse osmosis multilayer assembly is in fluid communication with said second outlet so as to permit passage of waste water from said second reverse osmosis multilayer assembly.

20      49. The apparatus according to claim 45 further comprising a generally cylindrical core disposed within said housing and extending generally from said base to said cap, said integral multilayer assembly being rolled about the outer surface of said cylindrical core so as to provide for spiral flow paths of the water being processed.

25      50. The apparatus according to claim 49 wherein said cylindrical core has a hollow central portion and said chemical means comprises activated carbon disposed within said hollow central portion.

51. The apparatus according to claim 50 further comprising filter plugs disposed at the ends of said hollow central portion so as to contain said activated carbon therebetween.

5 52. The apparatus according to claim 49 further comprising a second cylindrical hollow container having a base and an open end and being configured and dimensioned so as to be adapted to be positioned within said first container and to receive and to seal said first reverse osmosis  
10 multilayer assembly therein.

15 53. The apparatus according to claim 52 further comprising means disposed between said open end of said second cylindrical hollow container and said impermeable adhesive disposed along the central portion of said integral multilayer assembly so as to aid in sealing said first osmosis multilayer assembly within said second container.

20 54. The apparatus according to claim 53 wherein said sealing means comprises at least one O-ring.

55. The apparatus according to claim 53 wherein said sealing means comprises an impermeable sealant.

25 56. The apparatus according to claim 49 further comprising a second cylindrical hollow container having a base and an open end and being configured and dimensioned so as to be adapted to be positioned within said second container and to receive and to seal said second reverse  
30 osmosis multilayer assembly therein.

35 57. The apparatus according to claim 52 further comprising means disposed between said open end of said second cylindrical hollow container and said impermeable

adhesive disposed along the central portion of said integral multilayer assembly so as to aid in sealing said second osmosis multilayer assembly within said second container.

5 58. The apparatus according to claim 57 wherein  
said sealing means comprises at least one O-ring.

59. The apparatus according to claim 57 wherein  
said sealing means comprises an impermeable sealant.

10 60. The apparatus according to claim 49 wherein  
said reverse osmosis multilayer assembly after being rolled  
about the outer surface of said cylindrical core generally  
includes in a radially outwardly configuration from said  
surface, said porous permeate layer, said second reverse  
15 osmosis membrane layer, said porous mesh layer and said  
first reverse osmosis membrane layer.

20 61. The apparatus according to claim 60 wherein  
said nonporous semi-permeable membrane layers of said first  
and said second reverse osmosis membrane layers are disposed  
adjacent said porous mesh layer.

25 62. Apparatus for purifying water from a source  
comprising:

- a. housing having an inlet for passage of water  
from the source, a first outlet for passage of purified  
water from the passage of purified water from the  
housing and a second outlet for passage of waste water;
- 30 b. first reverse osmosis means disposed within  
said housing and being in fluid communication with said  
inlet for purification of at least a first portion of  
the water from the source;

5           c. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive said first purified portion of water for purification of at least a second portion of the purified water, said second reverse osmosis means also being in fluid communication with said second outlet for passage of waste water through said second outlet; and

10           d. chemical means being in fluid communication with said second reverse osmosis means to receive said second purified portion of water and for removal of at least chemical contaminants from said second purified portions of water, said chemical means also being in fluid communication with said first outlet so as to permit passage of said second portion of purified water through said first outlet.

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63. The apparatus according to claim 62 wherein said housing further comprises a third outlet for passage of waste water.

20

64. The apparatus according to claim 63 wherein said first reverse osmosis means is in fluid communication with said third outlet so as to permit passage of waste water through said third outlet.

25

65. The apparatus according to claim 62 wherein said first reverse osmosis means is disposed in an interleaf configuration with said second reverse osmosis means.

30

66. The apparatus according to claim 65 wherein said first reverse osmosis means comprises at least a first reverse osmosis multilayer assembly and said second reverse osmosis means comprises at least a second reverse osmosis multilayer assembly.

35

67. The apparatus according to claim 66 wherein said first and said second reverse osmosis multilayer assemblies are spirally rolled about a common axis.

5 68. The apparatus according to claim 67 wherein said first reverse osmosis multilayer assembly comprises:

- first reverse osmosis membrane layer;
- porous mesh layer;
- second reverse osmosis membrane layer; and
- first porous permeate layer.

10

69. The apparatus according to claim 68 wherein said second reverse osmosis multilayer assembly comprises:

- third reverse osmosis membrane layer;
- second porous permeate layer;
- fourth reverse osmosis membrane layer; and
- third porous permeate layer.

15

70. The apparatus according to claim 69 wherein said first, said second, said third and said fourth reverse osmosis membrane layers each comprises:

- nonporous semi-permeable membrane layer;
- porous ultrafiltration layer; and
- porous support layer.

25

71. The apparatus according to claim 70 wherein said semi-permeable membrane layer is formed generally of a solid nonporous continuous thin polymeric composition.

30

72. The apparatus according to claim 70 wherein said porous support layer is formed generally of polyamide.

73. The apparatus according to claim 72 wherein said polyamide is of a woven configuration.

35

74. The apparatus according to claim 72 wherein  
said polyamide is of a non-woven configuration.

75. The apparatus according to claim 69 wherein  
said housing includes an elongated hollow cylindrical  
5 container having a base and an open end.

76. The apparatus according to claim 75 wherein  
said housing includes a cap configured and dimensioned to  
10 fluidly seal said open end and including an inlet passageway  
for admitting water from the source, a first outlet  
passageway for purified water and a second outlet passageway  
for waste water.

77. The apparatus according to claim 76 wherein  
15 said cap further comprises a third outlet passageway for  
passage of waste water.

78. The apparatus according to claim 77 wherein  
said first reverse osmosis multilayer assembly is in fluid  
20 communication with said third outlet passageway for passage  
of waste water from said first reverse osmosis multilayer  
assembly.

79. The apparatus according to claim 76 further  
25 comprising a generally cylindrical core disposed within said  
housing and extending from said base to said cap, said  
integral multilayer assembly being rolled about the outer  
surface of said cylindrical core so as to provide for spiral  
flow paths of the water to be processed.  
30

80. The apparatus according to claim 79 wherein  
said cylindrical core has a hollow central portion and said  
chemical means is disposed within said hollow central  
portion.  
35

81. The apparatus according to claim 80 further comprising filter plugs disposed at the ends of said hollow central portion so as to contain said chemical means therebetween.

5       82. The apparatus according to claim 79 wherein the reverse osmosis multilayer assembly after being rolled about the outer surface of said cylindrical core generally includes in a radially outwardly configuration from said surface, said third porous permeate layer, said fourth  
10 reverse osmosis membrane layer, said second porous permeate layer, said third reverse osmosis membrane layer, said first porous permeate layer, said second reverse osmosis membrane layer, said porous mesh layer and said first reverse osmosis membrane layer.

15

83. The apparatus according to claim 82 wherein said nonporous semi-permeable membrane layers of said first and said second reverse osmosis membrane layers are disposed adjacent said porous mesh layer.

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84. The apparatus according to claim 83 wherein said nonporous semi-permeable membrane layers of said third and said fourth reverse osmosis membrane layers are disposed adjacent said second porous permeate layer.

25

85. Method for purifying water from a source comprising:

30       a. passing water from the source through a first reverse osmosis means being in fluid communication with the source so as to purify at least a first portion of the water from the source;

          b. passing the purified first portion of water

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through chemical means being in fluid communication with said first reverse osmosis means to receive said first purified portion of water and for removal of at least chemical contaminants from said first purified portions of water; and

- 5           c. passing the chemically purified water through a second reverse osmosis means being in fluid communication with said chemical means to receive the chemically purified water for purification of at least a second portion of the chemically purified water, said  
10          second reverse osmosis means also being in fluid communication with said first outlet and said second outlet so as to permit passage of said second portion of purified water through said first outlet and for passage of waste water through said second outlet.

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86. Method for purifying water from a source comprising:

- 20          a. passing water from the source through a first reverse osmosis means being in fluid communication with the source so as to purify at least a first portion of the water from the source;

- 25          b. passing the purified first portion of water through a second reverse osmosis means being in fluid communication with said first osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; and

- 30          c. passing the purified second portion of water through chemical means being in fluid communication with said second reverse osmosis means to receive said second purified portion of water and for removal of at least chemical contaminants from said purified second portion of water, said chemical means

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also being in fluid communication with said first outlet so as to permit passage of said chemically purified water through said first outlet.

87. The method according to claim 86 further  
5 comprising passing the chemically purified water through a filtration means for further purification.

88. Peritoneal dialysis system for treating a patient comprising:

- 10 a. reverse osmosis device for purifying water from a source and comprising:  
15     1. input means for coupling to the source of water;  
     2. first reverse osmosis means being in fluid communication with said input means for purification of at least a first portion of the water from the source; and  
     3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water;  
20 b. means for supplying a predetermined amount of drug;  
25 c. means for mixing the purified second portion of the water with the drug to provide a dialysate solution; and  
30 d. means for delivering the dialysate solution to the peritoneal cavity of the patient.

89. The system according to claim 88 further comprising means for draining waste water from said reverse osmosis device.

90. The system according to claim 89 further comprising means for draining spent dialysate solution from the peritoneal cavity of the patient.

5 91. The system according to claim 88 wherein said delivering means is adapted for continuous peritoneal dialysis treatment of the patient.

10 92. The system according to claim 88 wherein said delivering means is adapted for intermittent peritoneal dialysis treatment of the patient.

15 93. The system according to claim 88 wherein said delivering means is adapted for tidal peritoneal dialysis treatment of the patient.

94. The system according to claim 88 wherein said delivering means is adapted for continuous ambulatory peritoneal dialysis treatment of the patient.

20 95. The system according to claim 88 wherein said reverse osmosis device further comprises chemical means being in fluid communication with said first reverse osmosis means to receive said first purified portion of water and for removal of at least chemical contaminants from said first 25 purified portion of water before passing on to said second reverse osmosis means.

30 96. The system according to claim 88 further comprising a high pressure pump fluidly coupled between said source and said reverse osmosis device so as to provide sufficient pressure to allow for proper operation of said reverse osmosis device.

97. The system according to claim 96 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high pressure pump and said source so as to heat the water before purification.

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98. The system according to claim 96 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high pressure pump and said reverse osmosis device so as to heat the water before purification.

10

99. The system according to claim 95 wherein said reverse osmosis device further includes a first outlet for passage of purified water from the second reverse osmosis means and a second outlet for passage of waste water.

15

100. The system according to claim 99 wherein said reverse osmosis device further comprises a third outlet for passage of waste water.

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101. The apparatus according to claim 100 wherein said first osmosis means is in fluid communication with said third outlet so as to permit passage of waste water through said third outlet.

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102. The apparatus according to claim 101 wherein said second reverse osmosis means is in fluid communication with said second outlet for passage of waste water through said second outlet.

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103. The apparatus according to claim 99 wherein said second reverse osmosis means is in fluid communication with said second outlet for passage of waste water through said second outlet.

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104. The system according to claim 99 further comprising a heat exchanger means fluidly coupled to said second outlet of said reverse osmosis device and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from said waste water to the water to be heated.

105. The system according to claim 99 further comprising a heat exchanger means fluidly coupled to said means for draining spent dialysate solution and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from said solution to the water to be heated.

106. The system according to claim 88 wherein said supplying means comprises a storage container having a coupling end and containing a predetermined drug, and a metering system in fluid communication with said coupling end of said storage container to receive a predetermined amount of drug and further being in fluid communication with said purified second portion of the water after passing through said first outlet.

107. The system according to claim 106 further comprising means for sterilizing said coupling end of said storage container when being coupled and decoupled to said metering system.

108. The system according to claim 105 wherein said mixing means is in fluid communication with said first outlet and said metering system so as to receive said purified second portion of the water and said predetermined amount of drug for preparation of a dialysate solution.

109. The system according to claim 108 wherein  
said mixing means comprises an ultrasonic mixer.

110. The system according to claim 108 wherein  
said mixing means is an electromagnetic mixer.

5

111. The system according to claim 108 wherein  
said mixing means is an electromechanical mixer.

112. The system according to claim 108 wherein  
10 said mixing means is a static mixer.

113. The system according to claim 88 wherein said  
delivery means comprises a dual lumen catheter affixed to the  
patient and adapted for fluid communication at one end of one  
15 lumen with the peritoneal cavity of the patient and at the  
other end of said one lumen with said mixing means so as to  
allow for delivery of the dialysate solution to the  
peritoneal cavity.

20 114. The system according to claim 113 wherein one  
end of the other lumen is adapted for fluid communication  
with the peritoneal cavity of the patient and at the other  
end with a drain means to receive the spent dialysate  
solution.

25

115. The system according to claim 88 wherein said  
delivery means comprises a single lumen catheter affixed to  
the patient and adapted for fluid communication at one end of  
the lumen with the peritoneal cavity of the patient and at  
30 the other end of the lumen with said mixing means so as to  
allow for delivery of the dialysate solution to the  
peritoneal cavity and drainage of spent dialysate.

116. The system according to claim 88 further comprising pump means fluidly coupled between said supplying means and said reverse osmosis device.

117. The system according to claim 88 further  
5 comprising pump means fluidly coupled between said mixing means and the peritoneal cavity of the patient.

118. The system according to claim 88 further comprising pump means fluidly coupled between the peritoneal  
10 cavity of the patient and a drain means for receiving the spent dialysate solution.

119. The system according to claim 88 further comprising computer means for predetermined, selective and  
15 automatic control of said delivery means.

120. The system according to claim 88 further comprising computer means for predetermined, selective and  
20 automatic control of said supplying means.

121. The system according to claim 88 further comprising computer means for predetermined, selective and  
automatic control of said mixing means.

25 122. The system according to claim 89 further comprising computer means for predetermined, selective and automatic control of said draining means.

30 123. The system according to claim 88 wherein said reverse osmosis device further comprises chemical means being in fluid communication with said second reverse osmosis means to receive said second purified portion of water and for removal of at least chemical contaminants from said second purified portion of water.  
35

124. The system according to claim 123 further comprising a filtration means fluidly coupled to said chemical means for further purification of said second purified portion of water.

5

125. Method for treating a patient comprising:

a. purifying water from a source with a reverse osmosis device having:

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1. input means for coupling to the source of water;
2. first reverse osmosis means being in fluid communication with said input means for purification of at least a first portion of the water from the source; and

15

3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water.

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b. supplying a predetermined amount of drug;  
c. mixing the drug with the purified second portion of the water so as to provide a dialysate solution; and

25

d. delivering the dialysate solution to the peritoneal cavity of the patient.

30

126. The method according to claim 125 wherein delivery of the dialysate solution is continuous.

127. The method according to claim 125 wherein delivery of the dialysate solution is intermittent.

128. The method according to claim 125 wherein delivery of the dialysate solution is of the tidal mode of treatment.

129. The method according to claim 125 wherein  
5 delivery of the dialysate solution is of the continuous ambulatory mode of treatment.

130. The method according to claim 125 further comprising heating the water prior to purification.

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131. The method according to claim 125 further comprising pumping the water to said input means under a predetermined pressure prior to purification.

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132. The method according to claim 125 further comprising returning at least a portion of the waste water from the reverse osmosis device to heat exchanger means disposed in thermal relationship with the water from the source so as to provide for transfer of heat from said waste  
20 water to the water to be heated.

133. The method according to claim 125 further comprising returning at least a portion of the spent dialysate solution to heat exchanger means disposed in  
25 thermal relationship with the water from the source so as to provide for transfer of heat from said solution to the water to be heated.

134. The method according to claim 125 further comprising passing said first purified portion of water through chemical means being in fluid communication with said first reverse osmosis means for removal of at least chemical contaminants from said first purified portion of water before passing on to said second reverse osmosis means.

35

135. The method according to claim 125 further comprising passing said second purified portion of water through chemical means being in fluid communication with said second reverse osmosis means for removal of at least chemical contaminants from said second purified portion of water.

5

136. The method according to claim 135 further comprising passing said chemically treated water portion through a filtration means fluidly coupled to said chemical means for further purification of said water portion.

10

137. The method according to claim 125 further comprising draining waste water from said reverse osmosis device.

15

138. The method according to claim 125 further comprising draining spent dialysate solution from the peritoneal cavity of the patient.

20

139. System for supplying purified water from a source comprising:

a. reverse osmosis device for purifying the water from a source and having:

25

1. input means for coupling to the source of water;
2. first reverse osmosis means being in fluid communication with said input means for purification of at least a first portion of the water from the source; and

30

3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the

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purified first portion of water for  
further purification of at least a  
second portion of the water; and

- b. means for delivering the purified second  
portion of the water to either one of a storage means for  
5 future use and a control means for immediate predetermined  
use.

140. The system according to claim 139 wherein  
said reverse osmosis device further comprises chemical means  
10 being in fluid communication with said first reverse osmosis  
means to receive said first purified portion of water and for  
removal of at least chemical contaminants from said first  
purified portion of water before passing on to said second  
reverse osmosis means.

15

141. The system according to claim 139 wherein  
said reverse osmosis device further comprises chemical means  
being in fluid communication with said second reverse osmosis  
means to receive said second purified portion of water and  
20 for removal of at least chemical contaminants from said  
second purified portion of water.

142. The system according to claim 141 further  
comprising a filtration means fluidly coupled to said  
25 chemical means for further purification of said second  
purified portion of water.

143. Hemodialysis system for treating a patient  
comprising:

30 a. reverse osmosis device for purifying water  
from a source and having:

1. input means for coupling to the source of  
water;

35

2. first reverse osmosis means being in fluid communication with said input means for purification of at least a first portion of the water from the source; and

5       3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; and

10      b. means for supplying a predetermined amount of drug;

      c. means for mixing the purified second portion of the water with the drug to provide a dialysate solution; and

15      d. means for delivering the dialysate solution to a hemodialyzer.

144. The system according to claim 143 further comprising means for draining waste water from said reverse osmosis device.

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145. The system according to claim 144 further comprising means for draining spent dialysate solution from the hemodialyzer.

25

146. The system according to claim 143 wherein said reverse osmosis device further comprises chemical means being in fluid communication with said first reverse osmosis means to receive said first purified portion of water and for removal of at least chemical contaminants from said first purified portion of water before passing on to said second reverse osmosis means.

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147. The system according to claim 143 further comprising means for heating the water from the source, said heating means being coupled to the input means of the reverse osmosis device so as to heat the water before purification.

5 148. The system according to claim 143 further comprising a high pressure pump fluidly coupled between said source and said reverse osmosis device so as to provide sufficient pressure to allow for proper operation of said reverse osmosis device.

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149. The system according to claim 143 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high pressure pump and said source so as to heat the water before 15 purification.

150. The system according to claim 143 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high 20 pressure pump and said reverse osmosis device so as to heat the water before purification.

151. The system according to claim 143 wherein said reverse osmosis device further includes a first outlet 25 for passage of purified water from the second reverse osmosis means and a second outlet for passage of waste water.

152. The system according to claim 151 wherein said reverse osmosis device further comprises a third outlet 30 for passage of waste water.

153. The apparatus according to claim 152 wherein said first osmosis means is in fluid communication with said third outlet so as to permit passage of waste water through said third outlet.

5 154. The apparatus according to claim 153 wherein said second reverse osmosis means is in fluid communication with said second outlet for passage of waste water through said second outlet.

10 155. The apparatus according to claim 151 wherein said second reverse osmosis means is in fluid communication with said second outlet for passage of waste water through said second outlet.

15 156. The system according to claim 151 further comprising a heat exchanger means fluidly coupled to said second outlet of said reverse osmosis device and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from said waste water to the  
20 water to be heated.

25 157. The system according to claim 151 further comprising a heat exchanger means fluidly coupled to said means for draining spent dialysate solution and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from said solution to the water to be heated.

30 158. The system according to claim 143 wherein said supplying means comprises a storage container having a coupling end and containing a predetermined drug, and a metering system in fluid communication with said coupling end of said storage container to receive a predetermined amount

of drug and further being in fluid communication with said purified second portion of the water after passing through said first outlet.

159. The system according to claim 158 further  
5 comprising means for sterilizing said coupling end of said storage container when being coupled and decoupled to said metering system.

160. The system according to claim 143 wherein  
10 said mixing means is in fluid communication with said first outlet and said metering system so as to receive said purified second portion of the water and said predetermined amount of drug for preparation of a dialysate solution.

15 161. The system according to claim 160 wherein  
said mixing means comprises an ultrasonic mixer.

162. The system according to claim 160 wherein  
said mixing means is an electromagnetic mixer.

20 163. The system according to claim 160 wherein  
said mixing means is an electromechanical mixer.

164. The system according to claim 160 wherein  
25 said mixing means is a static mixer.

165. The system according to claim 143 further  
comprising pump means fluidly coupled between said supplying  
means and said reverse osmosis device.

30 166. The system according to claim 143 further  
comprising pump means fluidly coupled between said mixing  
means and the hemodialyzer.

167. The system according to claim 143 further comprising pump means fluidly coupled between the hemodialyzer and a drain means for receiving the spent dialysate solution.

5 168. The system according to claim 143 further comprising computer means for predetermined, selective and automatic control of said delivery means.

10 169. The system according to claim 143 further comprising computer means for predetermined, selective and automatic control of said supplying means.

15 170. The system according to claim 143 further comprising computer means for predetermined, selective and automatic control of said mixing means.

171. The system according to claim 143 further comprising computer means for predetermined, selective and automatic control of said draining means.

20 172. The system according to claim 143 wherein said reverse osmosis device further comprises chemical means being in fluid communication with said second reverse osmosis means to receive said second purified portion of water and 25 for removal of at least chemical contaminants from said second purified portion of water.

30 173. The system according to claim 172 further comprising a filtration means fluidly coupled to said chemical means for further purification of said second purified portion of water.

35 174. System for irrigating a portion of a patient's body comprising:

- a. reverse osmosis device for purifying water from a source and having:
1. input means for coupling to the source of water;
  2. first reverse osmosis means being in fluid communication with said input means for purification of at least a first portion of the water from the source; and
  3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; and
- b. means for supplying the purified second portion of the water to the portion of the patient's body.

175. System for irrigating a portion of a patient's body comprising:

- a. reverse osmosis device for purifying water from a source and having:
1. input means for coupling to the source of water;
  2. first reverse osmosis means being in fluid communication with said input means for purification of at least a first portion of the water from the source; and
  3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; and
- b. means for supplying a predetermined amount of drug;
- c. means for mixing the purified second portion

of the water with the drug to provide a drug solution; and

d. means for delivering the drug solution to the portion of the patient's body.

5        176. The system according to claim 175 wherein said reverse osmosis device further comprises chemical means being in fluid communication with said first reverse osmosis means to receive said first purified portion of water and for removal of at least chemical contaminants from said first  
10      purified portion of water before passing on to said second reverse osmosis means.

15        177. The system according to claim 176 further comprising means for heating the water from the source, said heating means being coupled to the input means of the reverse osmosis device so as to heat the water before purification.

20        178. The system according to claim 175 wherein said supplying means is adapted for irrigating a wound of a patient with said drug mixture.

25        179. The system according to claim 175 wherein said supplying means is adapted for irrigating a cavity of a patient's body with said drug mixture.

180. The system according to claim 175 wherein said supplying means includes a humidifying means which is adapted for humidification of a patient's lungs.

30        181. System for delivery of a predetermined injectable drug to a patient comprising:

a. reverse osmosis device for purifying water from a source and having:

1. input means for coupling to the source of  
water;

2. first reverse osmosis means being in fluid  
communication with said input means for  
purification of at least a first portion of the  
water from the source; and

5           3. second reverse osmosis means being in  
fluid communication with said first reverse osmosis  
means to receive the purified first portion of  
water for further purification of at least a second  
portion of the water; and

10           b. means for supplying and mixing the  
predetermined drug with said purified second portion of  
water; and

15           c. means for supplying said drug and purified  
water mixture to a body portion of the patient.

182. The system according to claim 181 wherein  
said reverse osmosis device further comprises chemical means  
being in fluid communication with said first reverse osmosis  
20           means to receive said first purified portion of water and for  
removal of at least chemical contaminants from said first  
purified portion of water before passing on to said second  
reverse osmosis means.

25           183. The system according to claim 181 further  
comprising means for heating the water from the source, said  
heating means being coupled to the input means of the reverse  
osmosis device so as to heat the water before purification.

30           184. The system according to claim 181 further  
comprising a high pressure pump fluidly coupled between said  
source and said reverse osmosis device so as to provide  
sufficient pressure to allow for proper operation of said  
reverse osmosis device.

185. Heat exchanger for transferring heat to a first source of fluid from a second source of fluid comprising:

- a. elongated core;
- b. first film composite having a first porous mesh and a first fluidly impermeable layer;
- 5 c. second film composite having a second porous mesh and a second fluidly impermeable layer; said first and said second membranes being disposed in an interleaved configuration and being disposed about said core so as to provide a first fluid flow path generally between said core and said first fluidly impermeable layer and a second fluid flow path between said first fluidly impermeable layer and said second fluidly impermeable layer such that heat from fluid in one of said first and 10 said second flow paths can be transferred to the fluid in said other flow path.
- 15

186. The heat exchanger according to claim 185 wherein said core is generally cylindrical and said 20 first and said second film composites are generally rectangular and are spirally rolled about said core.

187. The heat exchanger according to claim 185 wherein said first and said second fluidly impermeable 25 layers are each formed of a metallic foil.

188. The heat exchanger according to claim 185 wherein said first and said second fluidly impermeable 30 layers are each formed of an impermeable polymeric film.

189. The heat exchanger according to claim 185 wherein said first and said second fluidly impermeable layers are each formed of an impermeable inorganic film.

190. The heat exchanger according to claim 185 further comprising means for fluidly sealing said first and said second film composites along one edge to said core and also sealing to said core the adjacent edges transverse to said one edge.

5

191. The heat exchanger according to claim 188 wherein said sealing means comprises an impermeable adhesive.

10

192. The apparatus according to claim 185 further comprising an elongated hollow cylindrical housing container having a base and an open end.

15

193. The heat exchanger according to claim 192 wherein said housing container includes a cap configured and dimensioned to fluidly seal said open end and including an inlet passageway for admitting fluid from said first source, a first outlet for passage of said first source after heating, a second inlet for passage of said second source and a second outlet for passage of said second source after transfer of heat to said first source.

25

194. The heat exchanger according to claim 193 wherein said first inlet and said first outlet are in fluid communication with said first fluid path, and said second inlet and said second outlet are in fluid communication with said second fluid path.

30

195. Peritoneal dialysis system for treating a patient comprising:

a. reverse osmosis device for purifying water from a source and comprising:

35

1. housing having an inlet for passage of water from the source, a first outlet for passage of purified water from the housing and a second outlet for passage of waste water remaining after purification;

5           2. first reverse osmosis means disposed within said housing and being in fluid communication with said inlet for purification of at least a first portion of the water from the source, said first reverse osmosis means also being in fluid communication with said second outlet for passage of waste water through said second outlet; and

10           3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive said first portion of purified water for purification of at least a second portion of the purified water, said second reverse osmosis means also being in fluid communication with said first outlet so as to permit passage of said second portion of purified water through the first outlet; said reverse osmosis device being formed of radiation sterilizable components;

15           b. means for supplying a predetermined amount of drug;

20           c. means for mixing the purified second portion of the water with the drug to provide a dialysate solution; and

25           d. means for delivering the dialysate solution to the peritoneal cavity of the patient.

30

196. The system according to claim 195 wherein said supplying means is selectively replacable in the system.

197. The system according to claim 196 said supplying means is adapted for maintaining sterile fluid couplings and decouplings in the system.

198. The system according to claim 195 wherein 5 said mixing means is adapted for maintaining sterile fluid couplings and decouplings in the system.

199. The system according to claim 195 wherein 10 said delivering means is adapted for maintaining sterile fluid couplings and decouplings in the system.

200. The system according to claim 195 further comprising means for draining spent dialysate solution from the peritoneal cavity of the patient.

15

201. The system according to claim 200 wherein said draining means comprises a one way isolation valve to prevent any retrograde biocontamination of the peritoneal cavity of the patient.

20

202. The system according to claim 195 wherein 25 said reverse osmosis device further comprises chemical means being in fluid communication with said first reverse osmosis means to receive said first purified portion of water and for removal of at least chemical contaminants from said first purified portion of water before passing on to said second reverse osmosis means, said chemical means being radiation sterilizable.

30

203. The system according to claim 202 further comprising a high pressure pump fluidly coupled between said source and said reverse osmosis device so as to provide sufficient pressure to allow for proper operation of said reverse osmosis device.

35

204. The system according to claim 203 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high pressure pump and said source so as to heat the water before purification.

5

205. The system according to claim 203 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high pressure pump and said reverse osmosis device so as to heat 10 the water before purification.

206. The system according to claim 203 further comprising a heat exchanger means fluidly coupled to said second outlet of said reverse osmosis device and disposed in 15 thermal relationship with the water from the source so as to provide for transfer of heat from said waste water to the water to be heated.

207. The system according to claim 203 further 20 comprising a heat exchanger means fluidly coupled to said means for draining spent dialysate solution and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from said solution to the water to be heated.

25

208. The system according to claim 195 wherein 30 said supplying means comprises a storage container having a coupling end and containing a predetermined drug, and a metering system in fluid communication with said coupling end of said storage container to receive a predetermined amount of drug and further being in fluid communication with said purified second portion of the water after passing through said first outlet.

35

209. The system according to claim 208 further comprising means for sterilizing said coupling end of said storage container when being coupled and decoupled to said metering system.

5               210. The system according to claim 209 wherein said mixing means is in fluid communication with said first outlet and said metering system so as to receive said purified second portion of the water and said predetermined amount of concentrate for preparation of a dialysate  
10              solution.

211. The system according to claim 210 further comprising first pump means fluidly coupled between said mixing means and said reverse osmosis device.

15              212. The system according to claim 211 further comprising second pump means fluidly coupled between said mixing means and said supplying means.

20              213. The system according to claim 212 further comprising third pump means adapted to be fluidly coupled between said mixing means and the peritoneal cavity of the patient.

25              214. The system according to claim 213 further comprising fourth pump means adapted for fluid coupling between the peritoneal cavity of the patient and a drain means for receiving the used dialysate solution.

30              215. The system according to claim 214 wherein said first, said second, said third and said fourth pump means comprise volumetric pumps.

216. The system according to claim 215 wherein said volumetric pumps are calibratable.

217. The system according to claim 216 further comprising second supplying means adapted for fluid coupling  
5 to the peritoneal cavity of the patient for selective admission of a second predetermined drug.

218. The system according to claim 217 further comprising fifth pump means adapted for fluid coupling  
10 between said second supplying means and the peritoneal cavity of the patient.

219. The system according to claim 218 wherein  
said fifth pump means comprises a volumetric calibratable  
15 pump.

220. The system according to claim 219 further comprising clamp means for selective and independent operation of the components of the system.  
20

221. The system according to claim 220 wherein  
said clamp means comprises a plurality of on-off clamps disposed at predetermined fluid positions of the system.

25 222. The system according to claim 221 further comprising computer means coupled to said plurality of on-off claims for automatic predetermined operation thereof.

30 223. The system according to claim 195 wherein  
said housing includes an elongated hollow first cylindrical container having a base and an open end.

224. The system according to claim 223 further comprising a generally cylindrical core disposed within said housing and extending from said base to said cap, said first and said second reverse osmosis means being rolled about the outer surface of said cylindrical core so as to provide for spiral flow paths of the water to be processed.

5 225. The system according to claim 224 wherein said cylindrical core has a hollow central portion for receiving chemical means within said hollow central portion.

10 226. The system according to claim 225 further comprising a second cylindrical hollow container having a base and an open end and being configured and dimensioned so as to be adapted to be positioned within said first container, and to receive and to seal said first reverse osmosis means therein.

20 227. The system according to claim 225 wherein said housing includes a cap configured and dimensioned to fluidly seal said open end and including an inlet passageway for admitting water from the source, a first outlet passageway for purified water and a second outlet passageway for waste water.

25 228. The system according to claim 227 wherein said cap has an inner face and an outer face, said cap further comprising a plurality of protrusions extending from said inner face into selective contacting relationship with said core at predetermined positions, said protrusions being fusible with said core upon application of at least one of ultrasonic and thermal energy.

229. The system according to claim 228 wherein said second cylindrical container has an inner face and further comprises a plurality of protrusions extending from said inner face into selective contacting relationship with said core at predetermined positions.

5

230. The system according to claim 229 wherein said core has a plurality of passageways predeterminately coupled through said inner face of said cap and said inner face of said second container to provide fluid flow paths for 10 the water from the source, the waste water and the purified water into, through and out of said housing.

231. The system according to claim 195 further comprising at least a first conductivity sensor disposed 15 downstream of said source of purified water for monitoring of the conductivity of said water.

232. The system according to claim 231 further comprising at least a second conductivity sensor disposed 20 downstream of said mixing means for monitoring of the conductivity of said dialysate solution.

233. The system according to claim 232 further comprising computer means coupled to said first and said 25 second conductivity sensors for selective, predetermined operation of the system.

234. The system according to claim 233 further comprising means for restricting the flow of water there 30 through and also thereby through said reverse osmosis device.

235. The system according to claim 230 wherein said flow restricting means comprises a flow plug configured and dimensioned so as to be adapted to be disposed within at 35

least one passageway in said core, said flow plug having a reduced effective cross sectional area of a predetermined length than said at least one passageway so as to restrict the flow of water through said passageway and provide for  
5 predetermined pressures on either side of said flow plug.

236. The system according to claim 235 wherein said flow plug comprises a movable member disposed in said at least one passageway in said core so as to provide for variation in  
10 the effective length of the reduced cross-sectional area.

237. The system according to claim 236 wherein said movable member has a thread-like outer surface which allows said plug to be advanced in a screw-like member within said  
15 passageway.

238. The system according to claim 237 wherein said movable member has a slot-like opening at one end to receive a like configured tool for selectively moving said member within  
20 said passageway.

239. The system according to claim 235 comprising at least two flow plugs, each disposed in passageways in said core.

25

240. The system according to claim 195 wherein said reverse osmosis device further comprises chemical means being in fluid communication with said second reverse osmosis means to receive said second purified portion of water and for  
30 removal of at least chemical contaminants from said second purified portion of water, said chemical means being radiation sterilizable.

241. The system according to claim 240 further comprising a filtration means fluidly coupled to said chemical means for further purification of said second purified portion of water.

5 242. Method of manufacturing a reverse osmosis device on a core for purifying water from a source comprising:

a. providing an integral reverse osmosis multilayer assembly having:

10 1. first reverse osmosis membrane layer;  
2. porous mesh layer;  
3. second reverse osmosis membrane layer; and  
4. porous permeate layer;

15 b. sealing a central portion of said integral multilayer assembly;

c. sealing at least one edge of each reverse osmosis membrane layer of said multilayer assembly to the core;

20 d. sealing along two opposed side edges of said integral multilayer assembly;

e. rolling said integral multilayer assembly in a spiral configuration on the core; and

25 f. bonding said seals by induction heating so as to fluidly seal said integral multilayer assembly along said edges and said central portion and so as to separate said integral multilayer assembly into a first reverse osmosis multilayer assembly and a second reverse osmosis multilayer assembly.

30 243. Method of manufacturing a reverse osmosis device on a core for purifying water from a source comprising:

a. providing an integral reverse osmosis multilayer assembly having:

1. first reverse osmosis membrane layer;
  2. porous mesh layer;
  3. second reverse osmosis membrane layer; and
  4. porous permeate layer;
- b. disposing an impermeable adhesive along the length of a central portion of said integral multilayer assembly;
- 5 c. disposing an impermeable adhesive along the side edges of said integral multilayer assembly;
- d. rolling said integral multilayer assembly in a 10 spiral configuration on a core; and
- e. bonding said adhesive by induction heating so as to fluidly seal said integral multilayer assembly along said edges and said central portion and so as to separate said integral multilayer assembly into a first reverse 15 osmosis multilayer assembly and a second reverse osmosis multilayer assembly.

244. The method according to claim 243 further comprising enclosing said spirally rolled and bonded integral 20 multilayer assembly in a housing having an inlet for passage of water for a source, a first outlet for passage of purified water from the passage of purified water from the housing and a second outlet for passage of waste water remaining after purification, disposing said first reverse osmosis multilayer 25 assembly within said housing in fluid communication with said inlet for purification of at least a first portion of the water from the source, and disposing said second reverse osmosis multilayer assembly within said housing in fluid communication with said first reverse osmosis means to 30 receive said first purified portion of water for purification of at least a second portion of the purified water, said second reverse osmosis means also being disposed in fluid communication with said second outlet for passage of waste water through said second outlet.

245. Method of manufacturing on a core a reverse osmosis device for purifying water from a source comprising:

a. providing an integral reverse osmosis multilayer assembly having:

1. first reverse osmosis membrane layer;
- 5 2. porous mesh layer;
3. second reverse osmosis membrane layer;
4. first porous permeate layer;
5. third reverse osmosis membrane layer;
6. second porous permeate layer;
- 10 7. fourth reverse osmosis membrane layer; and
8. third porous permeate layer;

b. sealing at least an edge of each reverse osmosis membrane layer of said integral multilayer assembly to a core;

15 c. sealing along two opposed side edges of said integral multilayer assembly;

d. rolling said integral multilayer assembly in a spiral configuration on the core; and

20 e. bonding said seal by induction heating so as to fluidly seal said integral multilayer assembly along said edges.

246. Method of manufacturing on a core a reverse osmosis device for purifying water from a source comprising:

25 a. providing an integral reverse osmosis multilayer assembly having:

1. first reverse osmosis membrane layer;
2. porous mesh layer;
3. second reverse osmosis membrane layer;
- 30 4. first porous permeate layer;
5. third reverse osmosis membrane layer;
6. second porous permeate layer;
7. fourth reverse osmosis membrane layer; and
8. third porous permeate layer;

- 
- 
- 
- 
- b. disposing an impermeable adhesive along at least an edge of each reverse osmosis membrane layer of said integral multilayer assembly and disposing said edge to a core;
  - c. disposing an impermeable adhesive along two opposed side edges of said integral multilayer assembly;
  - d. rolling said integral multilayer assembly in a spiral configuration on the core; and
  - e. bonding said impermeable adhesives by induction heating so as to fluidly seal said integral multilayer assembly along said edges.
- 10

247. The method according to claim 246 further comprising enclosing said spirally rolled and bonded integral multilayer assembly in a housing having an inlet for passage of water from a source, a first outlet for passage of purified water from the housing and a second outlet for passage of waste water remaining after purification, disposing said reverse osmosis multilayer assembly within said housing so that said first and said second reverse osmosis membrane layers and said first porous mesh layer are in fluid communication with said inlet for purification of at least a first portion of the water from the source, and disposing said first and said second porous permeate layers and said third and said fourth reverse osmosis layers within said housing in fluid communication with said first and said second reverse osmosis membrane layers to receive said first purified portion of water for purification of at least a second portion of the purified water, said first and said second porous permeate layer and said first porous mesh layer being in fluid communication with said second outlet for passage of waste water through said second outlet, and said third porous permeate layer being in fluid communication with said first outlet for passage of purified water through said first outlet.

248. Device for sterile coupling and decoupling of a drug container to a delivery system, the container having an open end and a puncturable seal adapted for entry into the open end so as to seal the open end comprising:

- a. housing configured and dimensioned for
- 5 receiving and cooperating with the plug so as to provide a fluid tight cooperating engagement when the plug enters said housing;
- b. barrier means disposed within said housing and having a portion thereof adapted for sterile penetration of
- 10 said barrier means by a conduit of the delivery system;
- c. an inlet duct and an outlet duct disposed through said housing and disposed between said barrier means and the plug when positioned within said housing, said inlet duct adapted for fluid coupling to a source of sterilizing
- 15 fluid, and said outlet duct adapted for fluid coupling to reservoir container to receive said sterilizing fluid after passing across the portion of the plug facing said barrier means.

20 249. Hemofiltration system for treating a patient comprising:

- a. reverse osmosis device for purifying water from a source and having:
  1. input means for coupling to the source of water;
  2. first reverse osmosis means being in fluid communication with said input means for purification of at least a first portion of the water from the source; and
  - 30 3. second reverse osmosis means being in fluid communication with said first reverse osmosis means to receive the purified first portion of water for further purification of at least a second portion of the water; and

b. means for supplying a predetermined amount of drug;

c. means for mixing the purified second portion of the water with the drug to provide a blood make up solution; and

5 d. means for delivering the blood make up solution to the concentrated blood outlet of a hemoultrafilter.

250. The system according to claim 249 further  
10 comprising means for draining waste water from said reverse osmosis device.

251. The system according to claim 250 further comprising means for draining spent waste solution from the  
15 hemofilter.

252. The system according to claim 249 wherein said reverse osmosis device further comprises chemical means being in fluid communication with said first reverse osmosis  
20 means to receive said first purified portion of water and for removal of at least chemical contaminants from said first purified portion of water before passing on to said second reverse osmosis means.

253. The system according to claim 249 further comprising means for heating the water from the source, said heating means being coupled to the input means of the reverse osmosis device so as to heat the water before purification.

254. The system according to claim 249 further comprising a high pressure pump fluidly coupled between said source and said reverse osmosis device so as to provide sufficient pressure to allow for proper operation of said reverse osmosis device.

255. The system according to claim 249 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high pressure pump and said source so as to heat the water before purification.

5

256. The system according to claim 249 further comprising means for heating the water from the source, said heating means being fluidly coupled between said high pressure pump and said reverse osmosis device so as to heat the water before purification.

10

257. The system according to claim 249 wherein said reverse osmosis device further includes a first outlet for passage of purified water from the second reverse osmosis means and a second outlet for passage of waste water.

15

258. The system according to claim 257 wherein said reverse osmosis device further comprises a third outlet for passage of waste water.

20

259. The apparatus according to claim 258 wherein said first osmosis means is in fluid communication with said third outlet so as to permit passage of waste water through said third outlet.

25

260. The apparatus according to claim 259 wherein said second reverse osmosis means is in fluid communication with said second outlet for passage of waste water through said second outlet.

30

261. The apparatus according to claim 257 wherein said second reverse osmosis means is in fluid communication with said second outlet for passage of waste water through said second outlet.

35

262. The system according to claim 257 further comprising a heat exchanger means fluidly coupled to said second outlet of said reverse osmosis device and disposed in thermal relationship with the water from the source so as to provide for transfer of heat from said waste water to the  
5 water to be heated.

263. The system according to claim 257 further comprising a heat exchanger means fluidly coupled to said means for draining spent waste solution and disposed in  
10 thermal relationship with the water from the source so as to provide for transfer of heat from said solution to the water to be heated.

264. The system according to claim 249 wherein  
15 said supplying means comprises a storage container having a coupling end and containing a predetermined drug, and a metering system in fluid communication with said coupling end of said storage container to receive a predetermined amount of drug and further being in fluid communication with said  
20 purified second portion of the water after passing through said first outlet.

265. The system according to claim 264 further comprising means for sterilizing said coupling end of said  
25 storage container when being coupled and decoupled to said metering system.

266. The system according to claim 249 wherein  
30 said mixing means is in fluid communication with said first outlet and said metering system so as to receive said purified second portion of the water and said predetermined amount of drug for preparation of the blood make up solution.

267. The system according to claim 266 wherein  
said mixing means comprises an ultrasonic mixer.

268. The system according to claim 266 wherein  
said mixing means is an electromagnetic mixer.

5

269. The system according to claim 266 wherein  
said mixing means is an electromechanical mixer.

270. The system according to claim 266 wherein  
10 said mixing means is a static mixer.

271. The system according to claim 249 further  
comprising pump means fluidly coupled between said supplying  
means and said reverse osmosis device.

15

272. The system according to claim 249 further  
comprising pump means fluidly coupled between said mixing  
means and the hemofilter.

20

273. The system according to claim 249 further  
comprising pump means fluidly coupled between the  
hemofilter and a drain means for receiving the spent  
waste solution.

25

274. The system according to claim 249 further  
comprising computer means for predetermined, selective and  
automatic control of said delivery means.

30

275. The system according to claim 249 further  
comprising computer means for predetermined, selective and  
automatic control of said supplying means.

276. The system according to claim 249 further comprising computer means for predetermined, selective and automatic control of said mixing means.

277. The system according to claim 249 further  
5 comprising computer means for predetermined, selective and automatic control of said draining means.

278. The system according to claim 249 wherein  
said reverse osmosis device further comprises chemical means  
10 being in fluid communication with said second reverse osmosis  
means to receive said second purified portion of water and  
for removal of at least chemical contaminants from said  
second purified portion of water.

15 279. The system according to claim 278 further  
comprising a filtration means fluidly coupled to said  
chemical means for further purification of said second  
purified portion of water.

20

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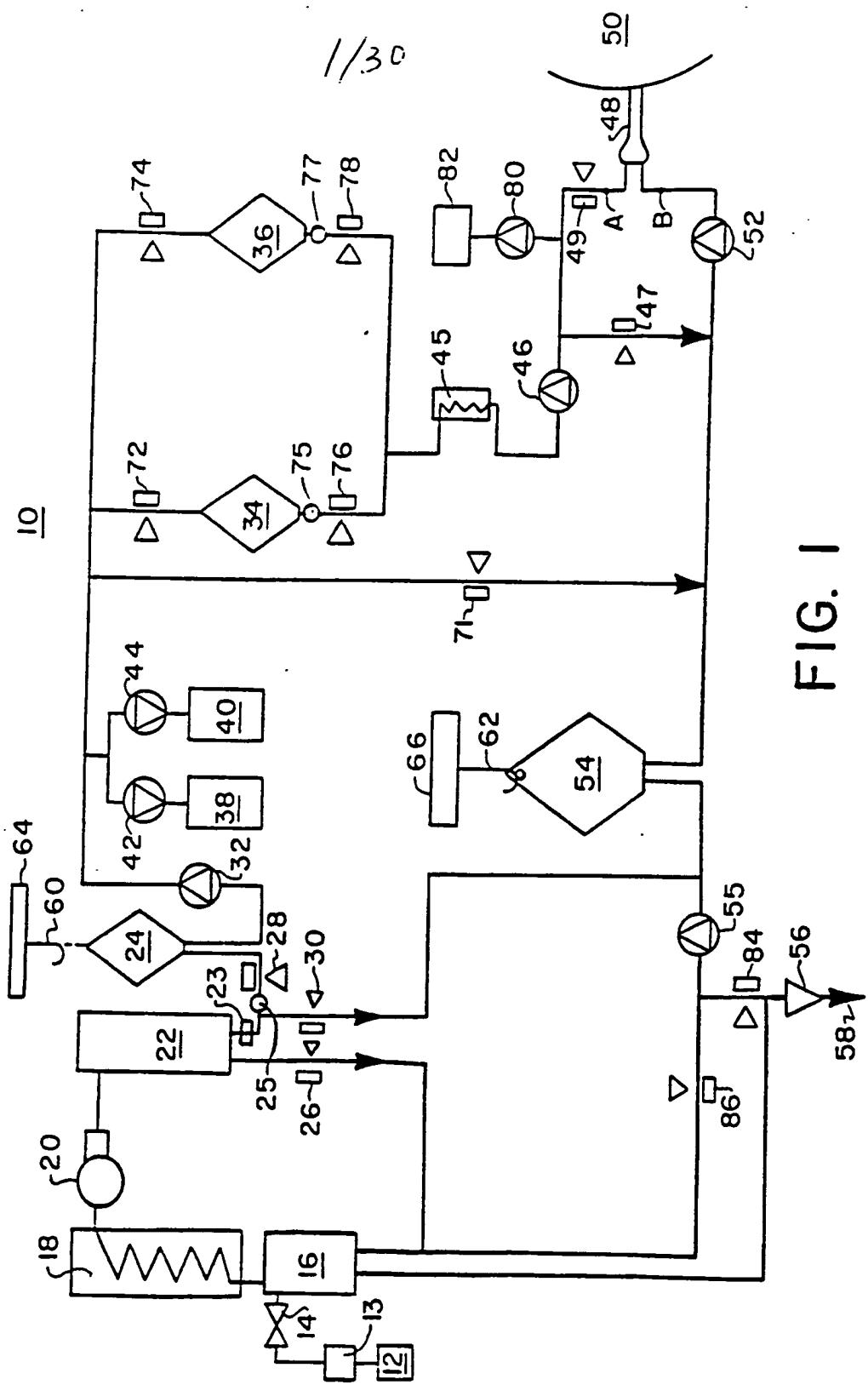


FIG. I

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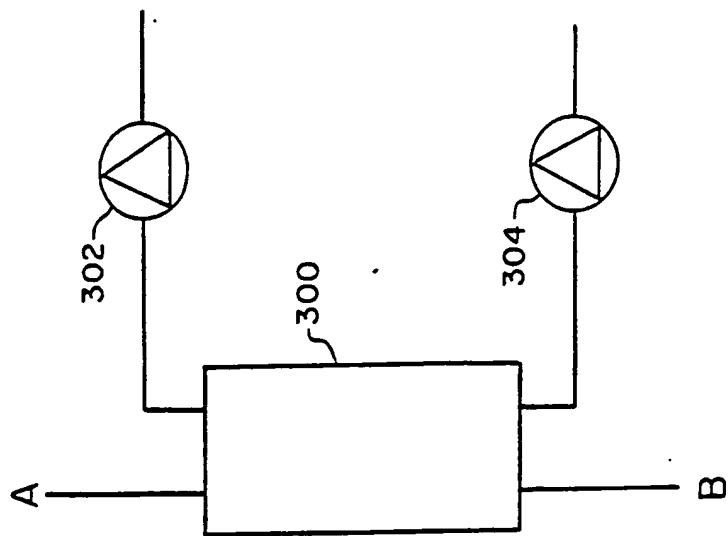


FIG. 3

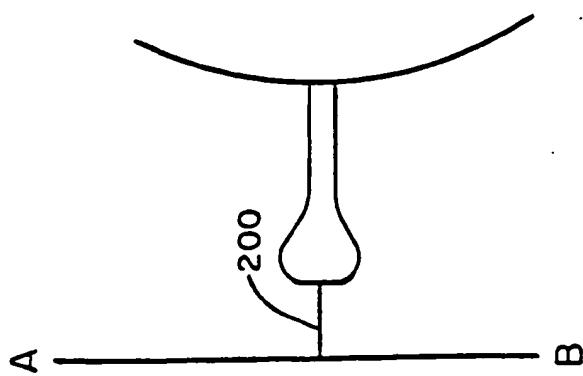


FIG. 2

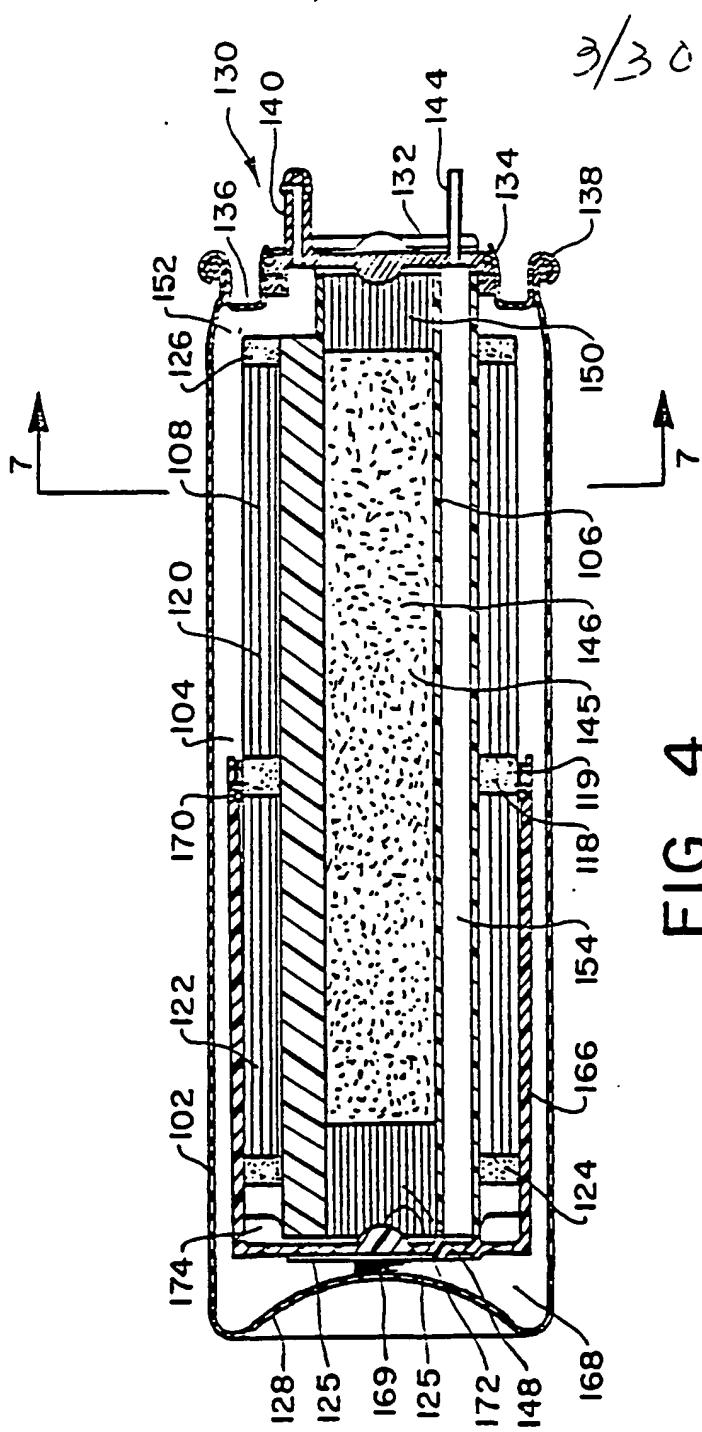


FIG. 4.

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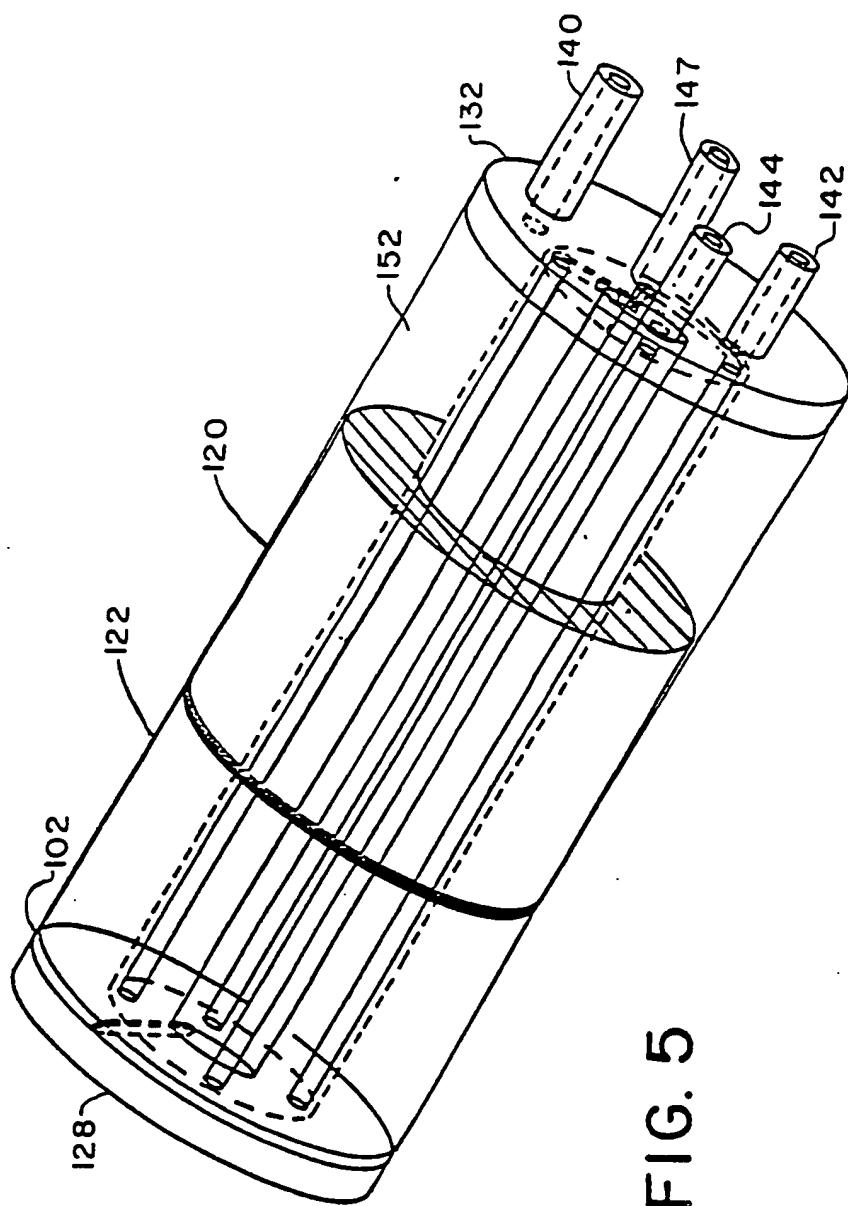


FIG. 5

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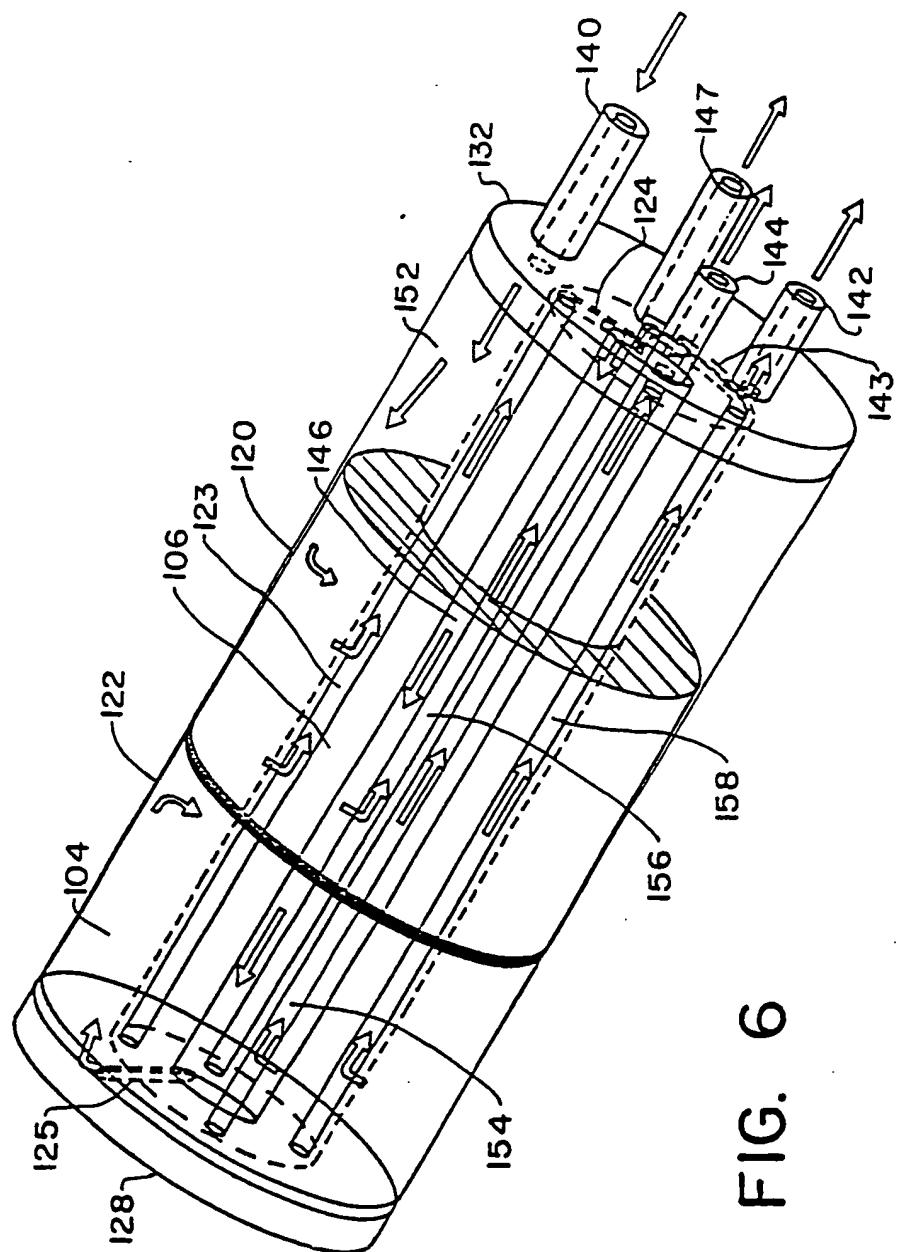


FIG. 6

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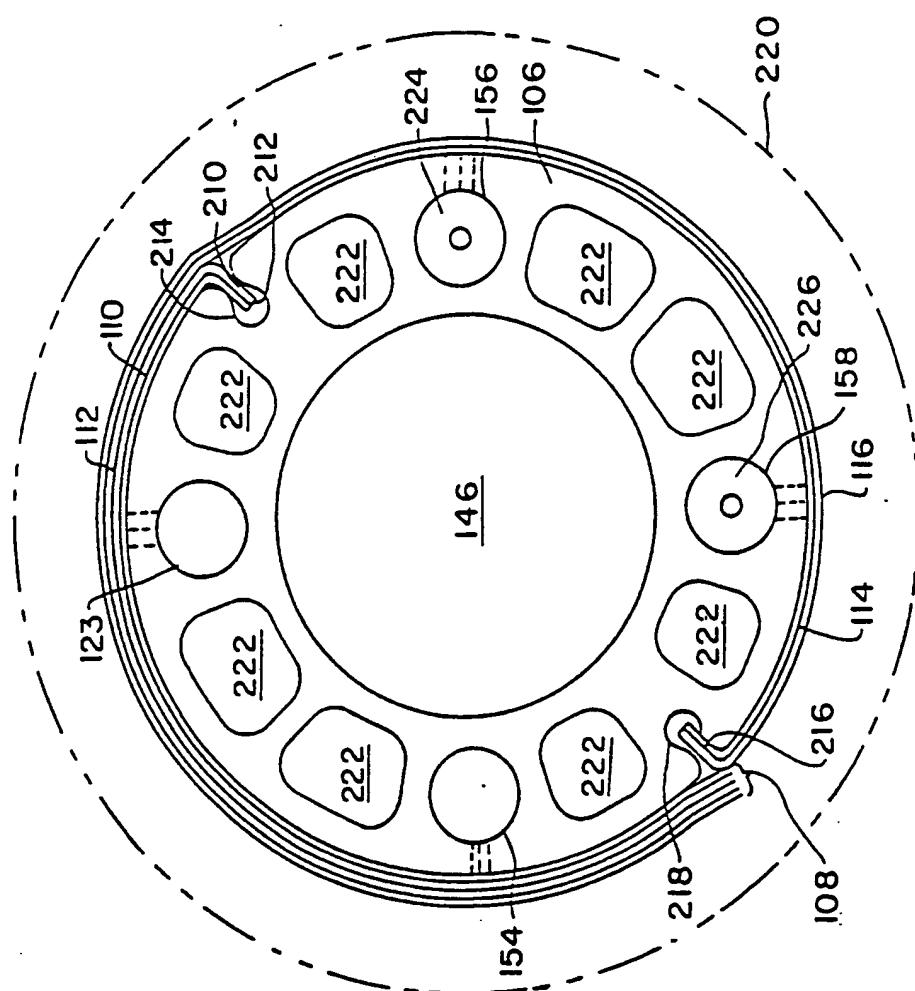


FIG.

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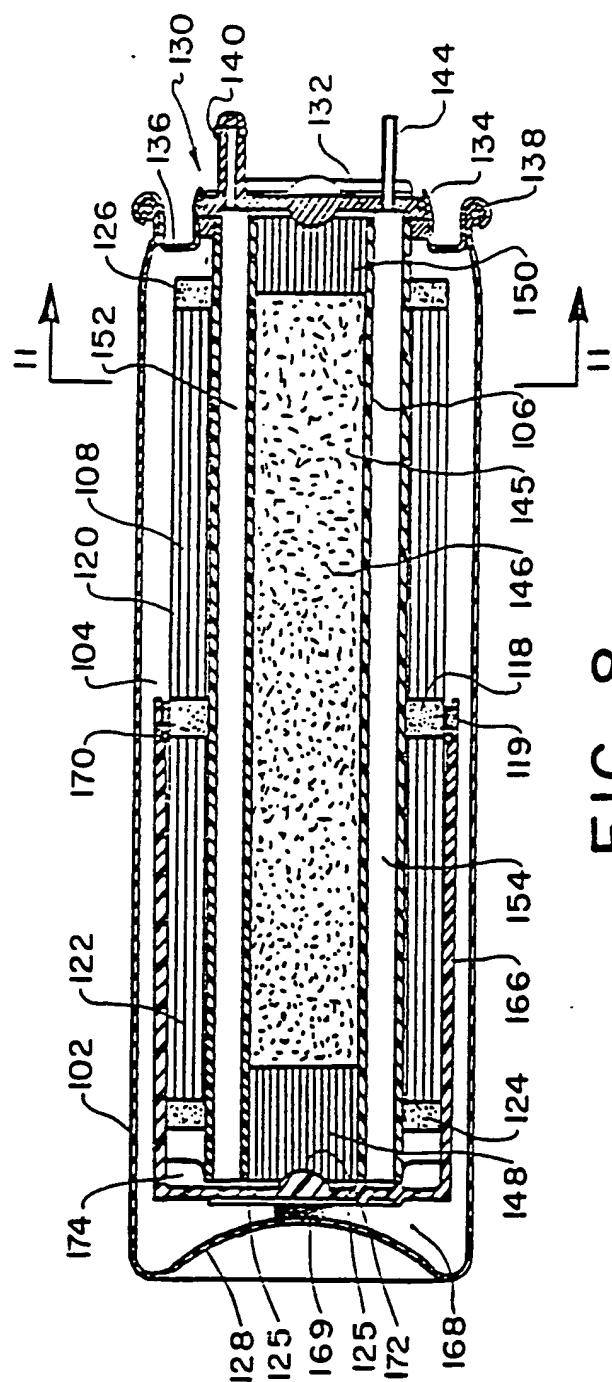


FIG. 8

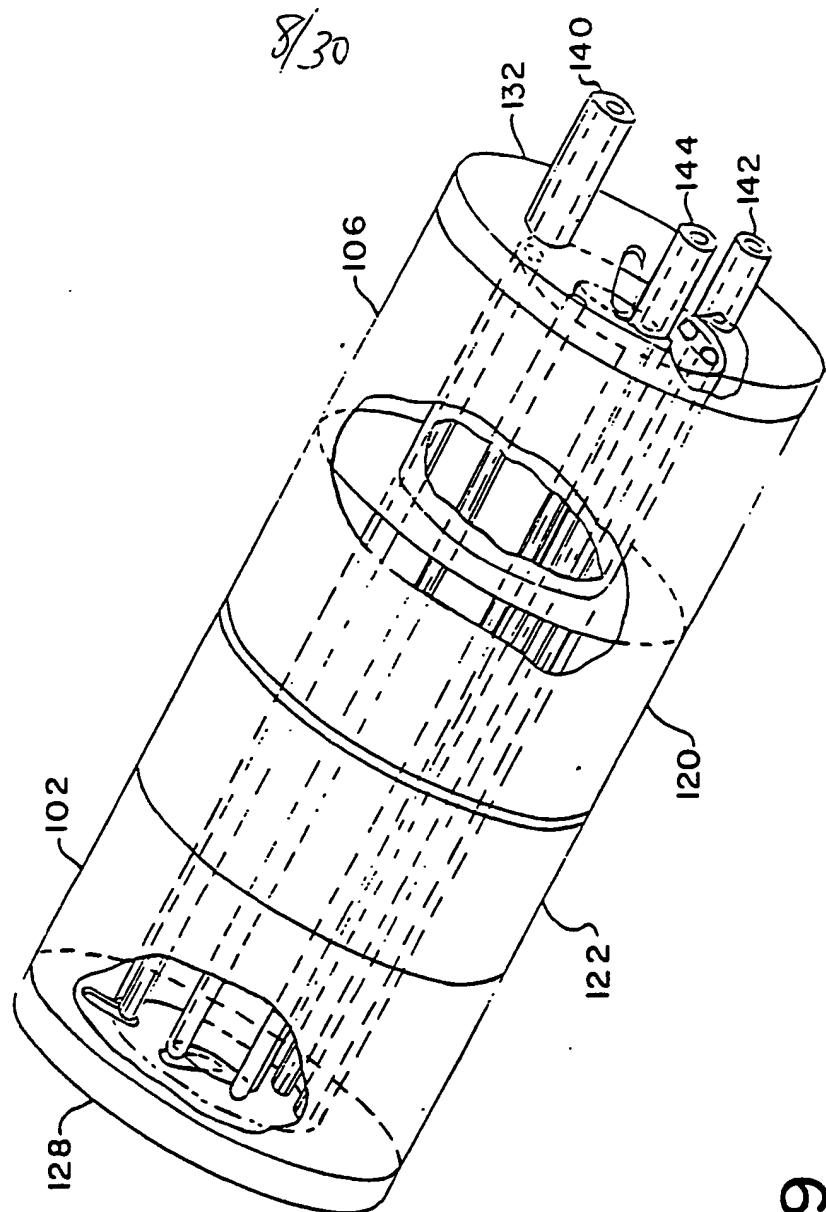


FIG. 9

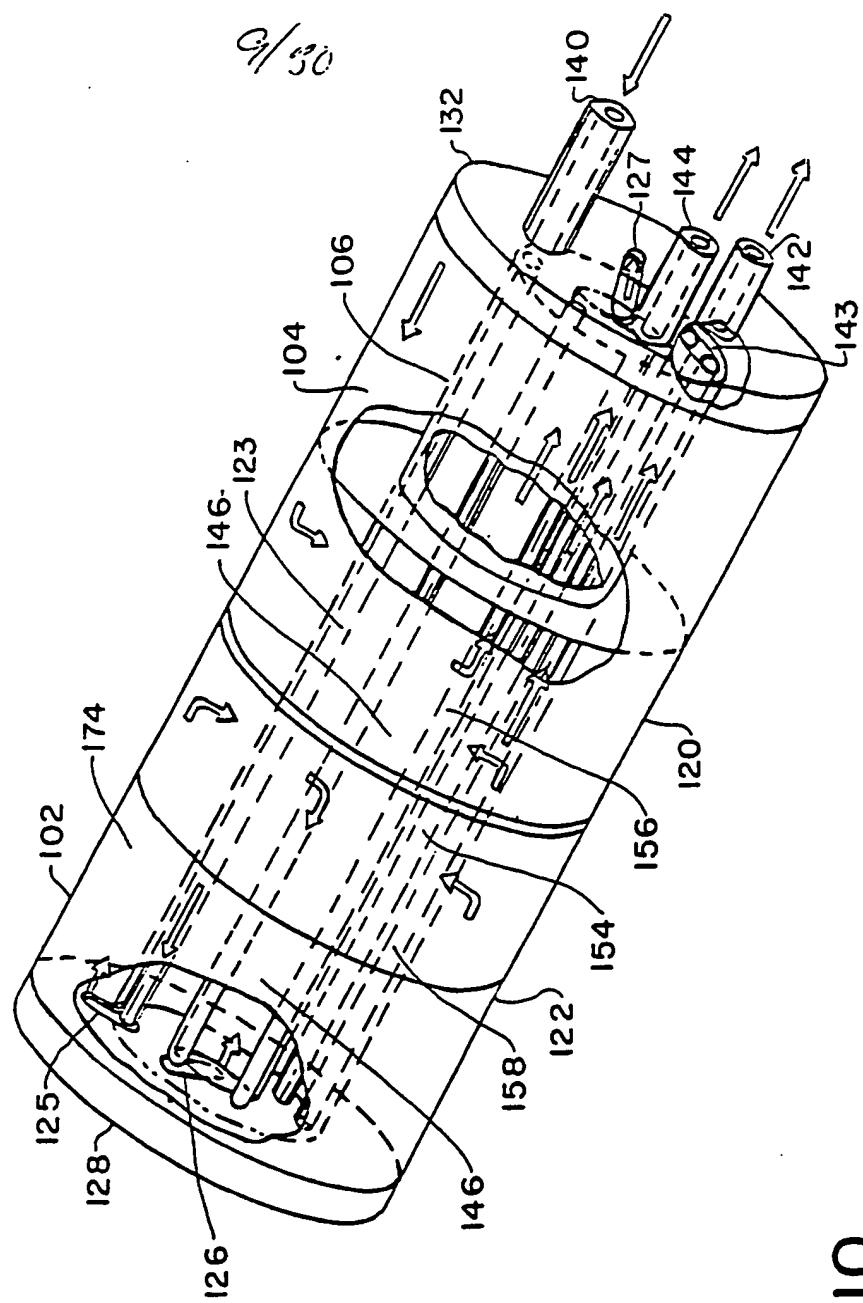


FIG. 10

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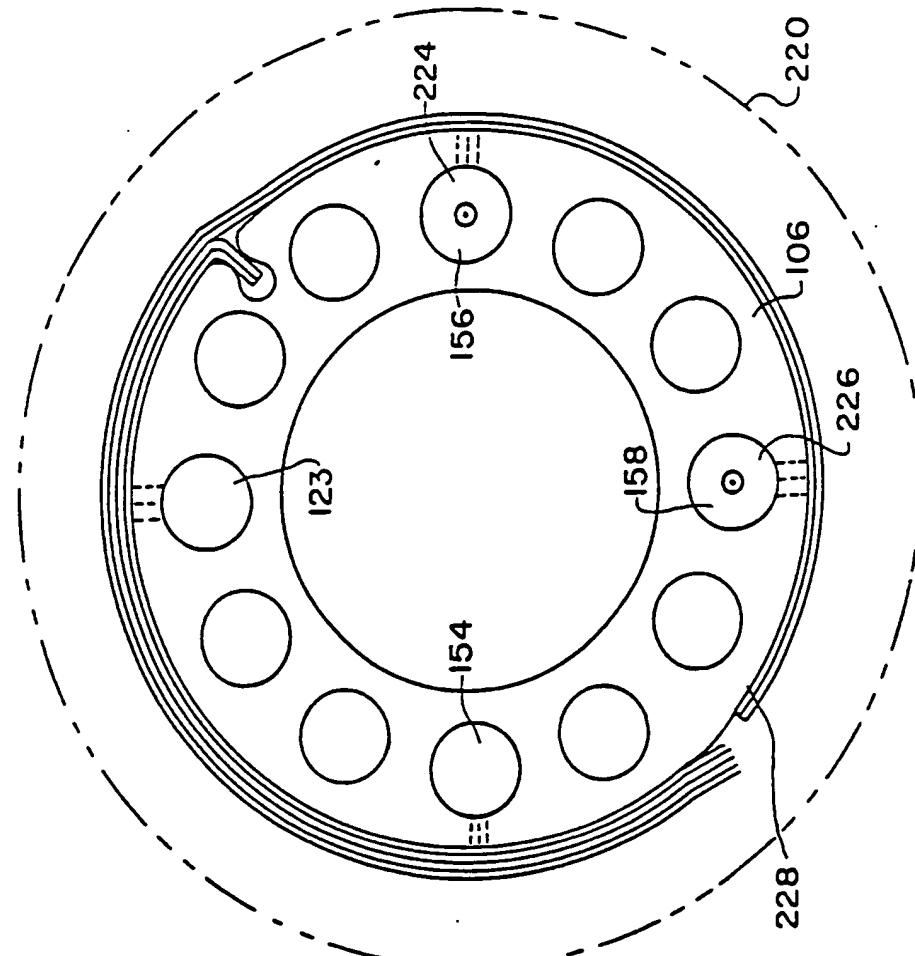


FIG. II

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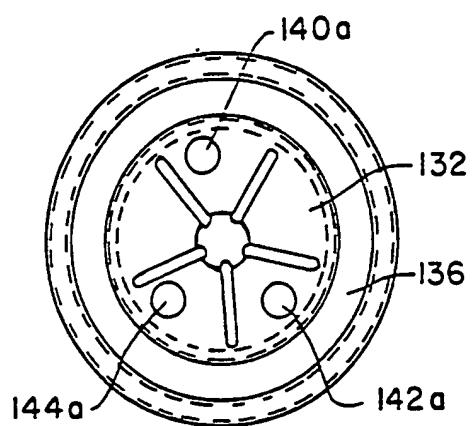


FIG. 12

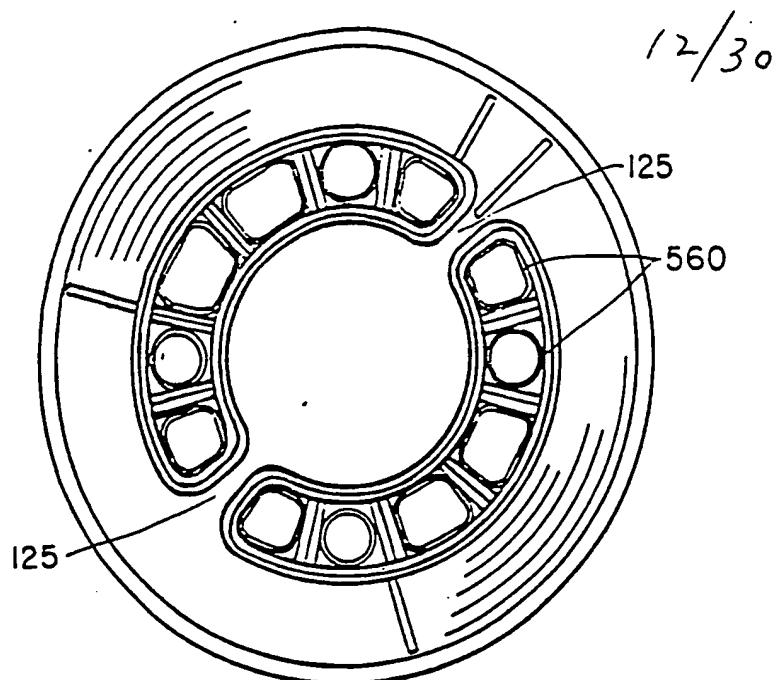


FIG. I2 B

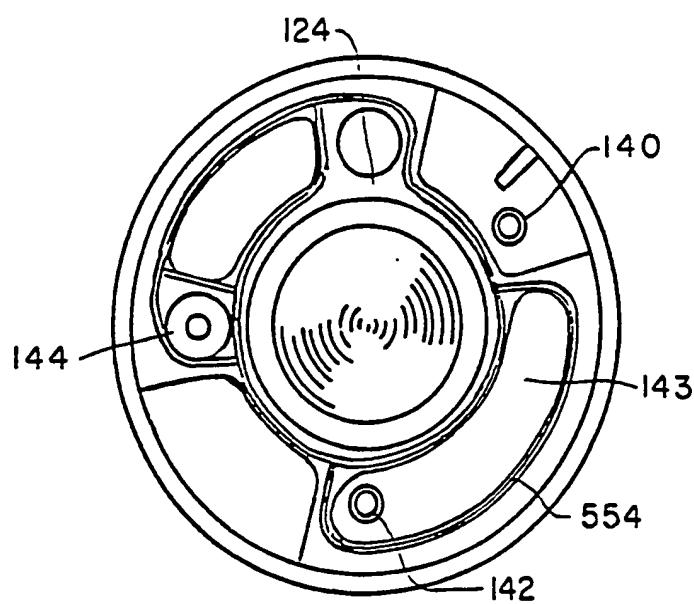
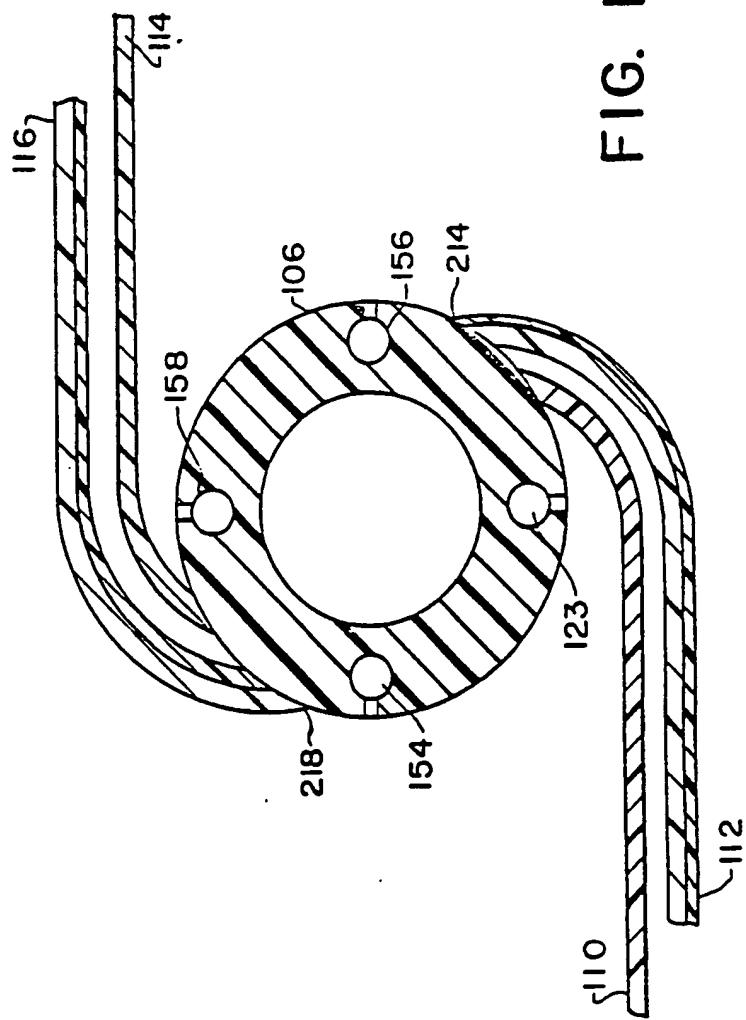


FIG. I2A

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FIG. 13



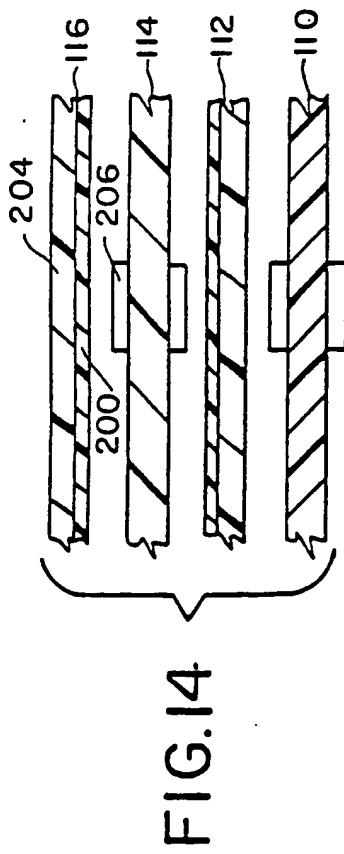
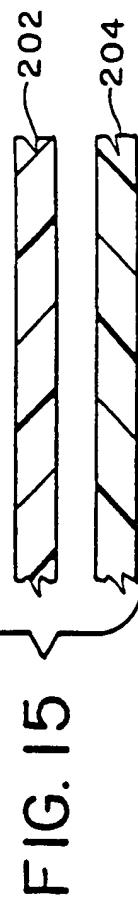
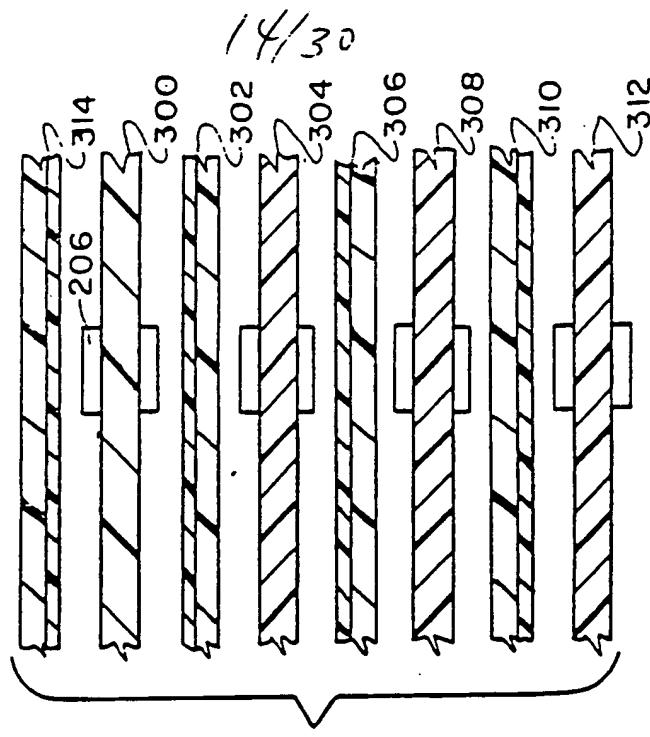


FIG. 19



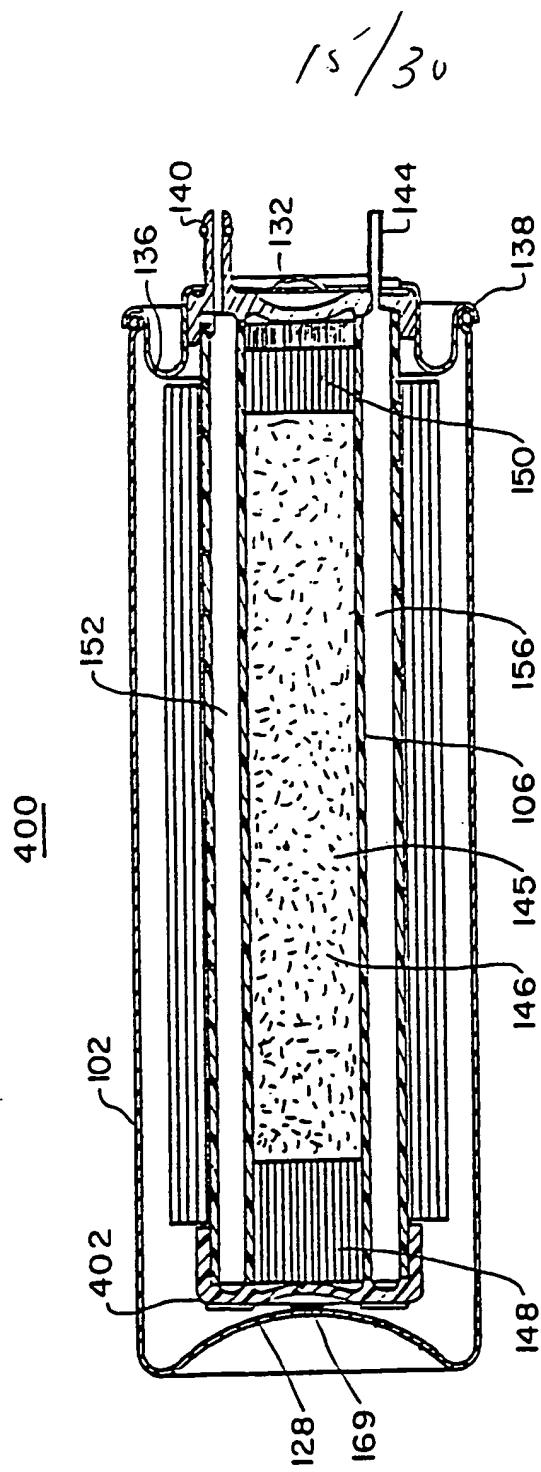


FIG. 16

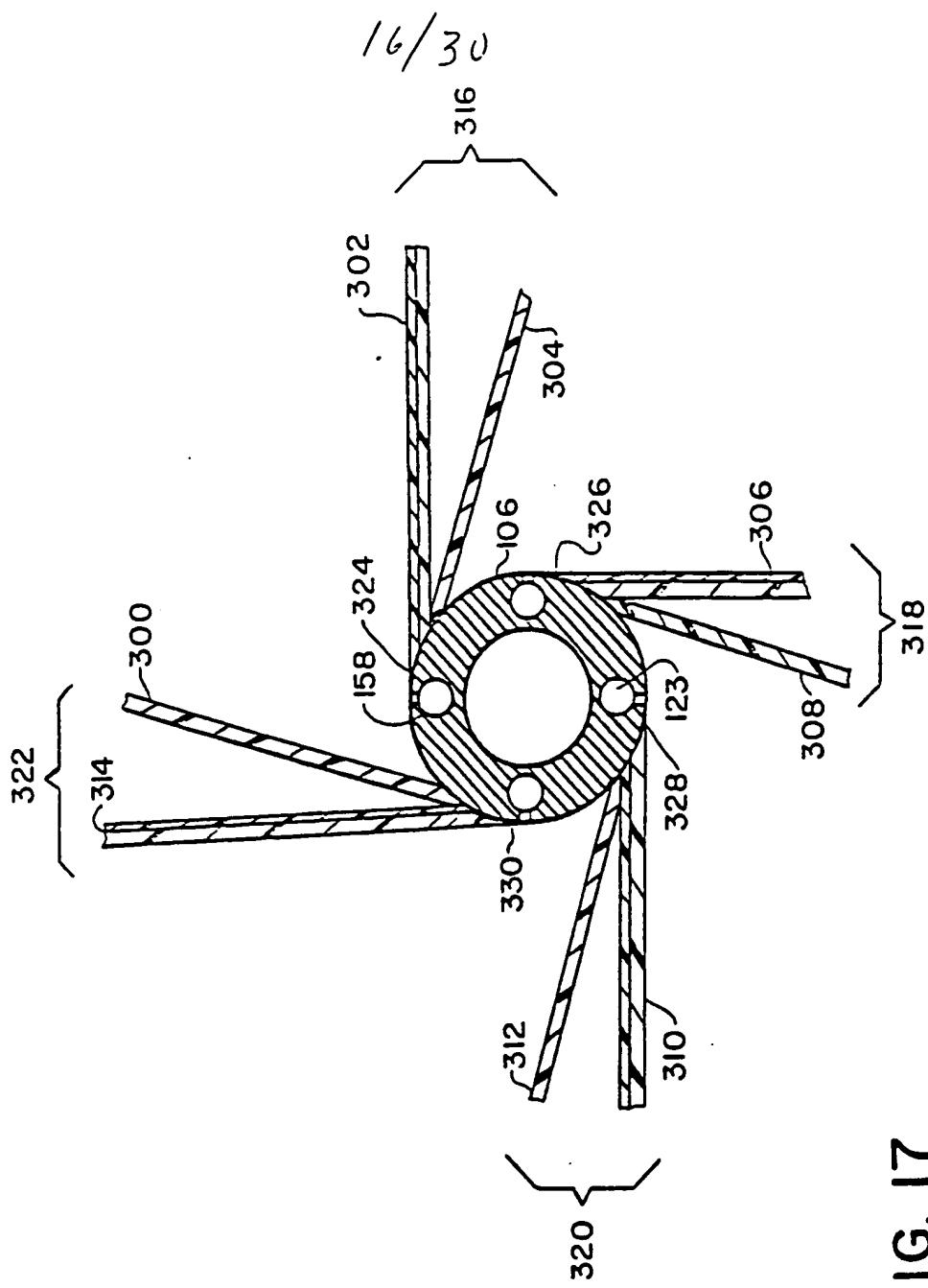


FIG. 17

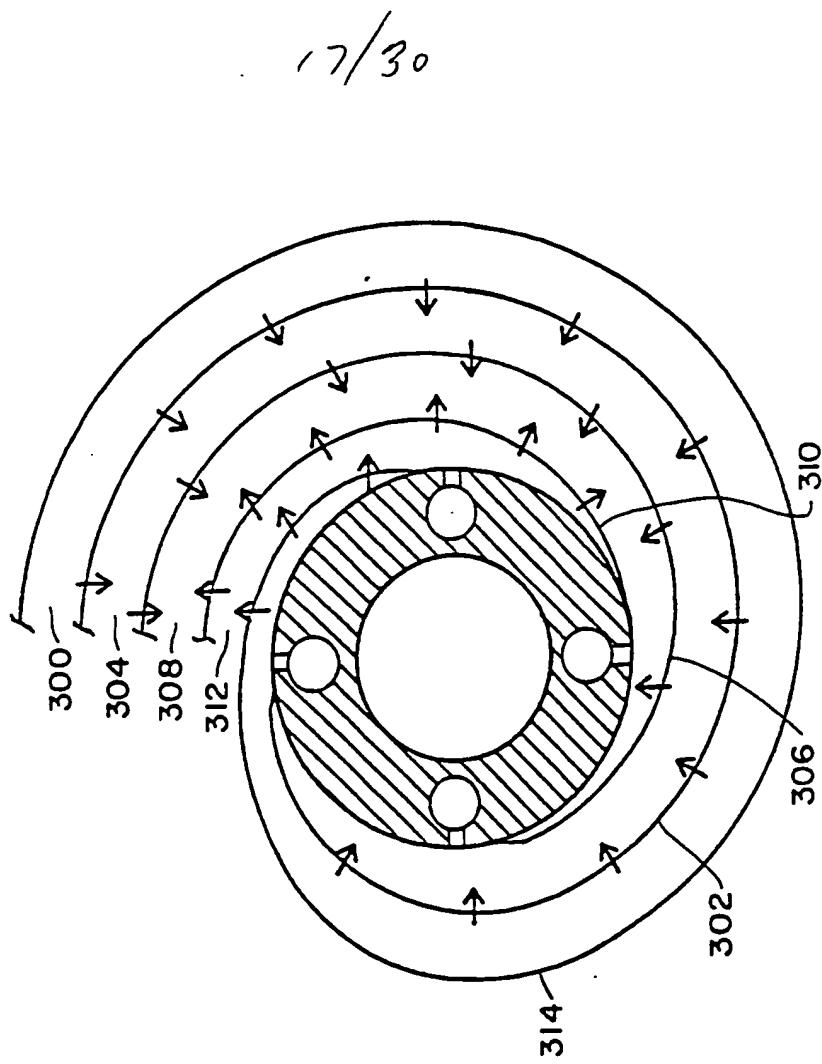
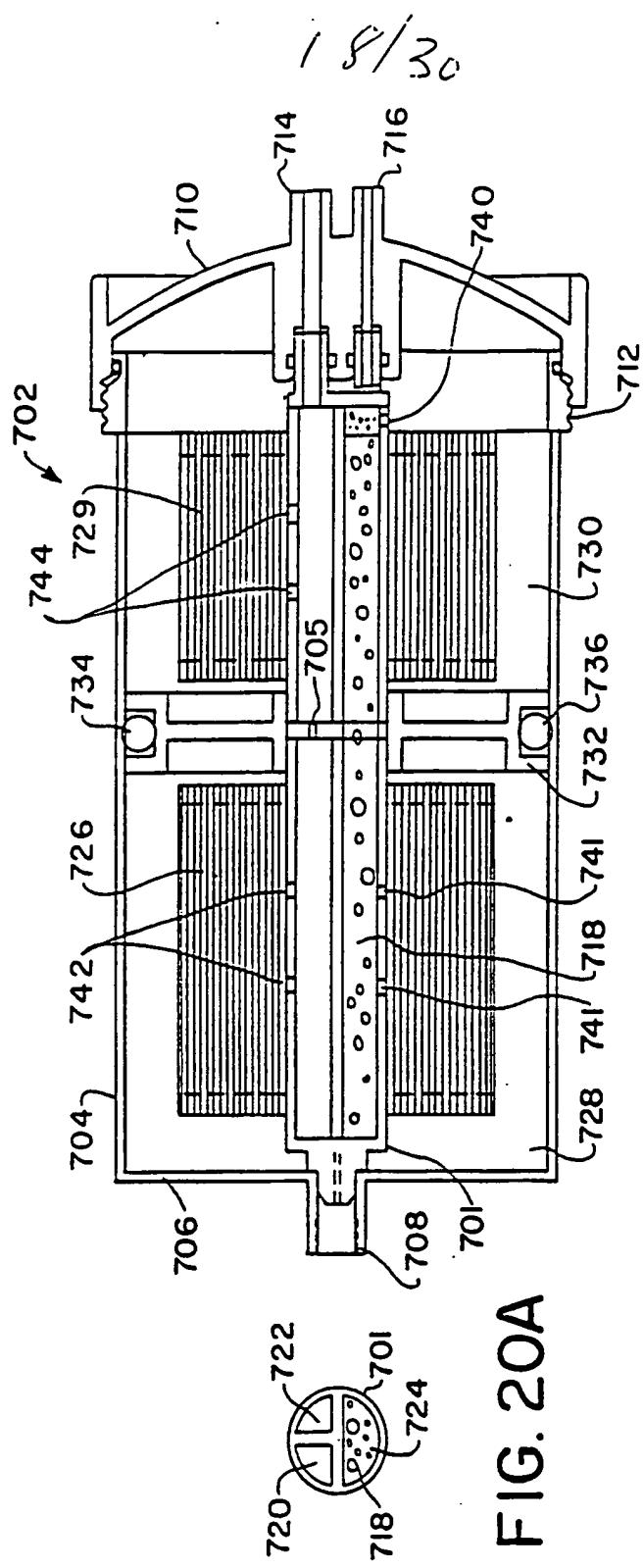


FIG. 18



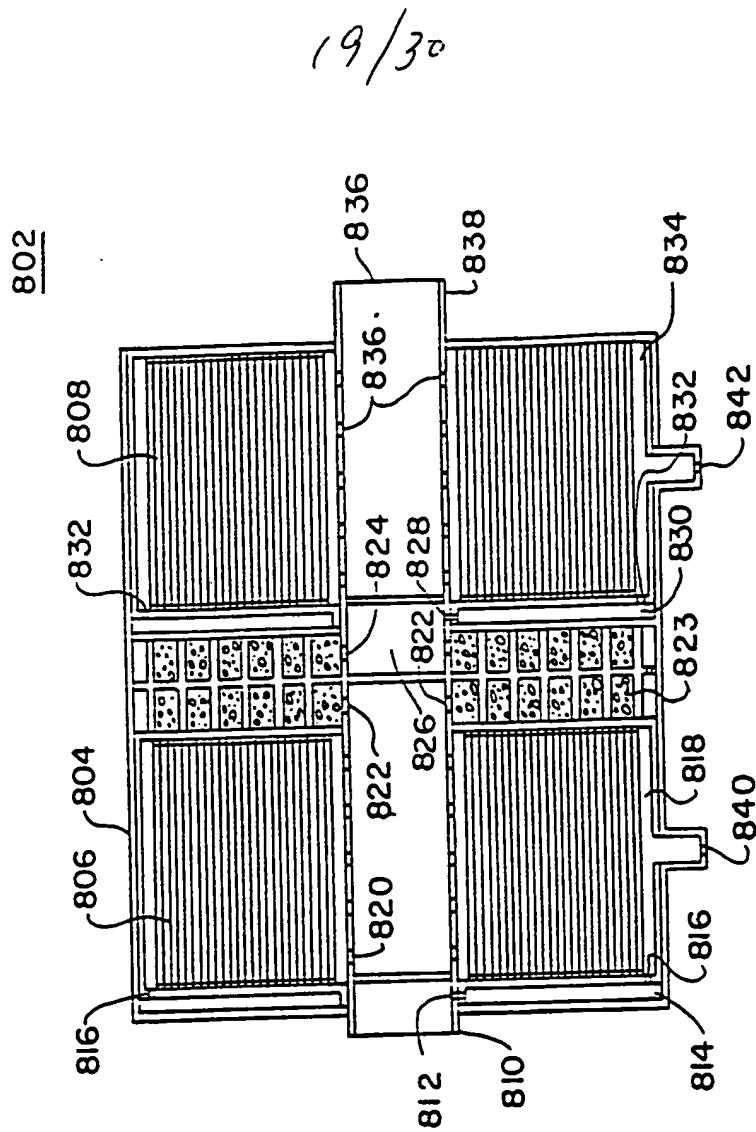


FIG. 21

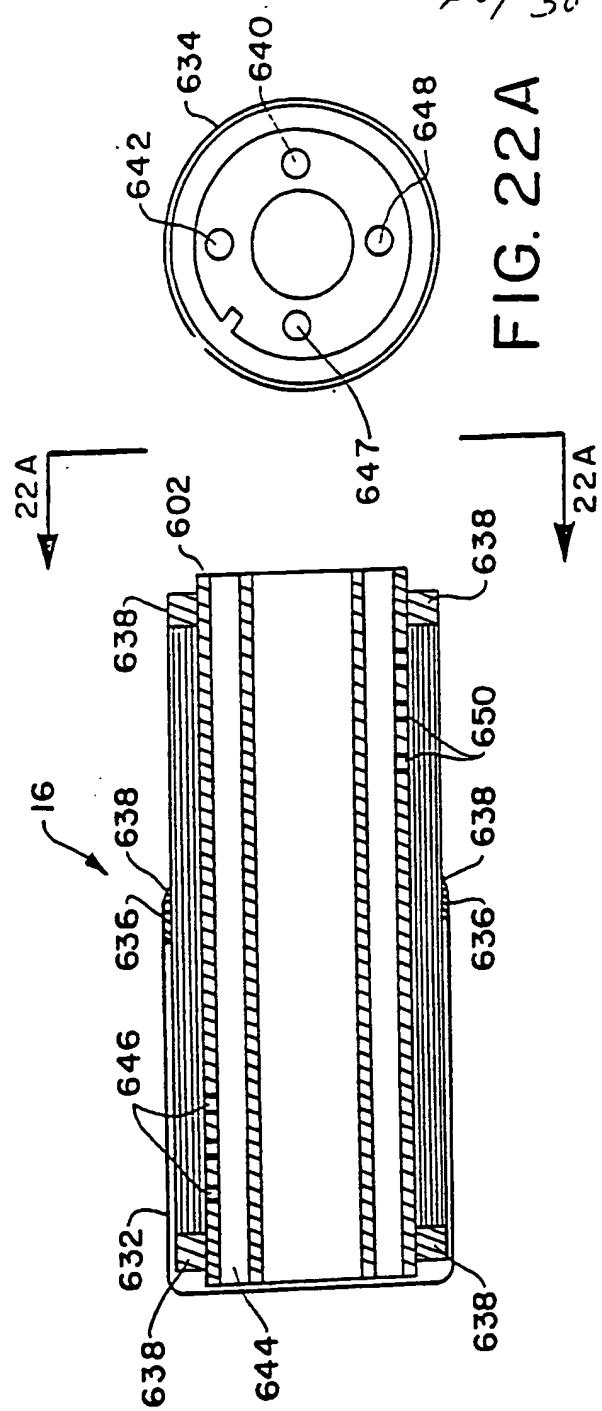


FIG. 22

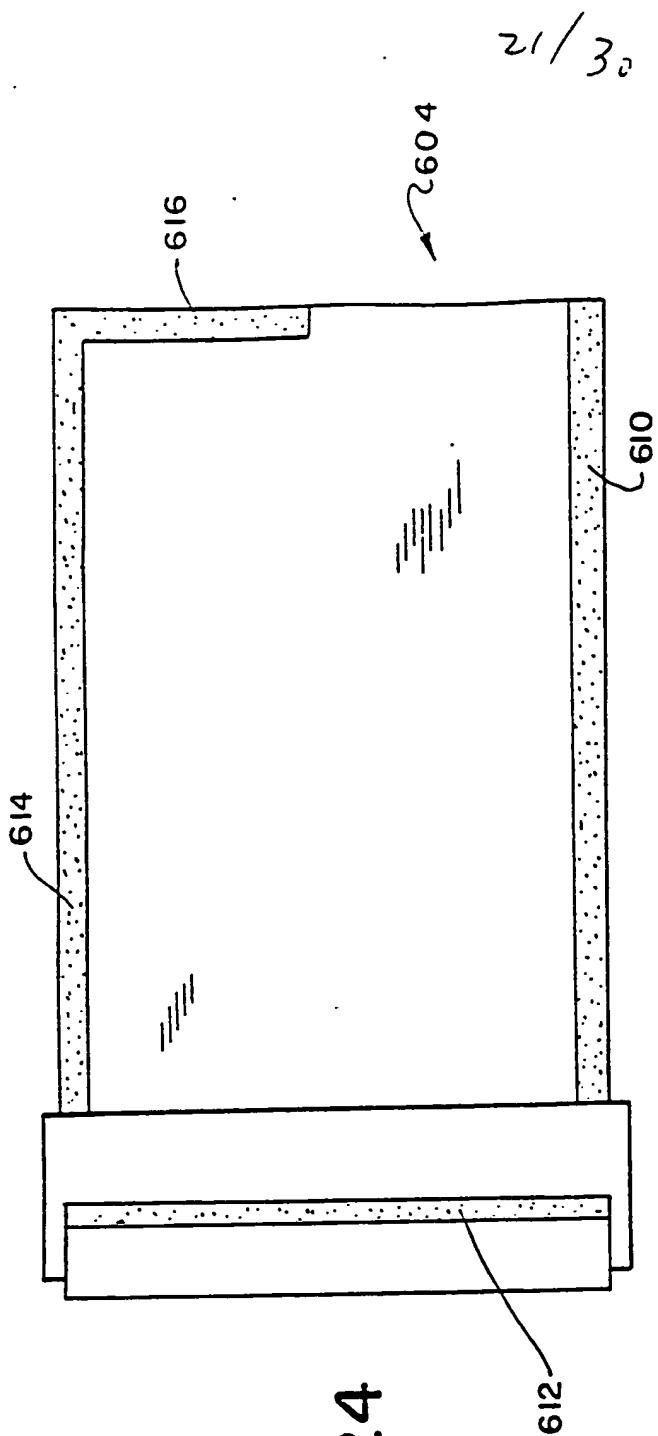


FIG. 24

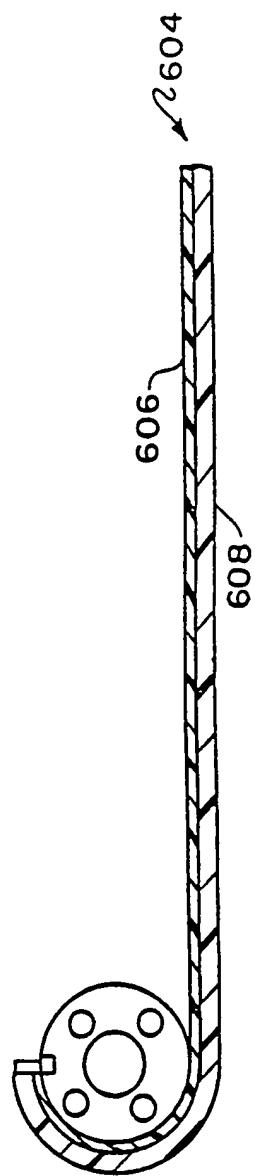


FIG. 23

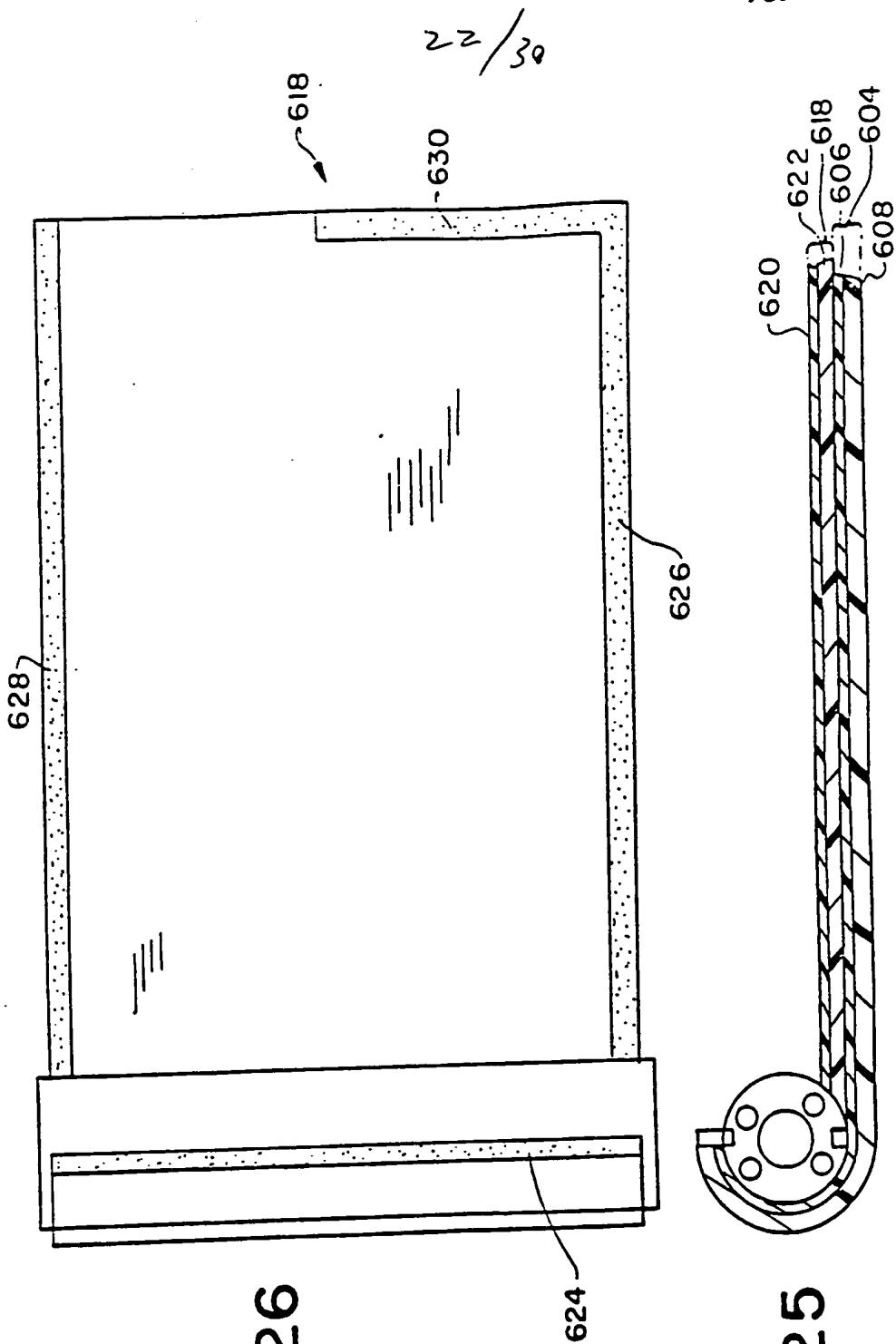


FIG.26

FIG.25

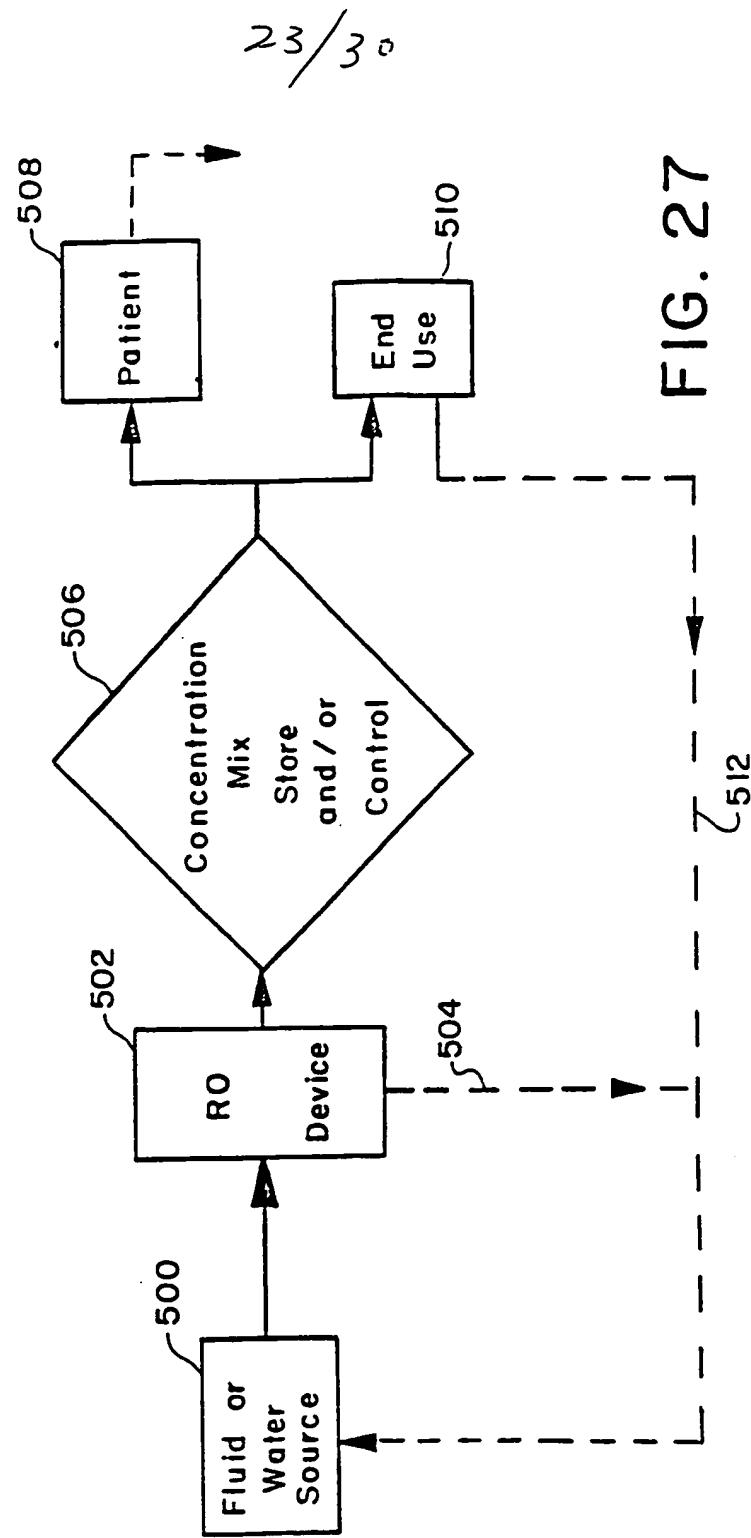


FIG. 27

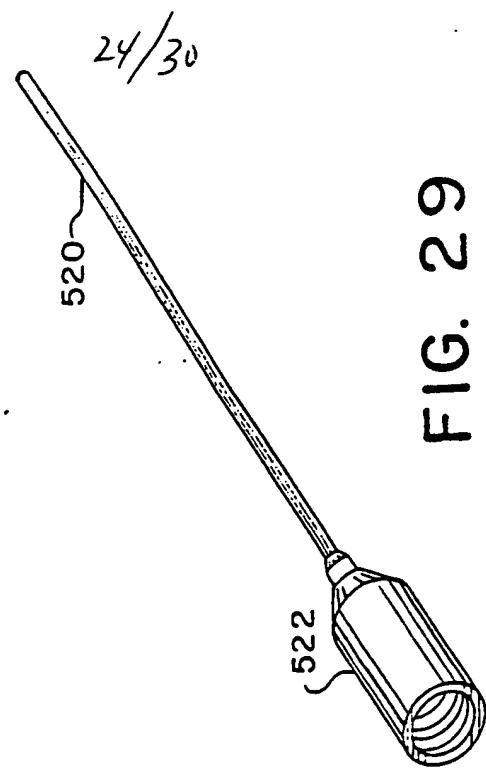
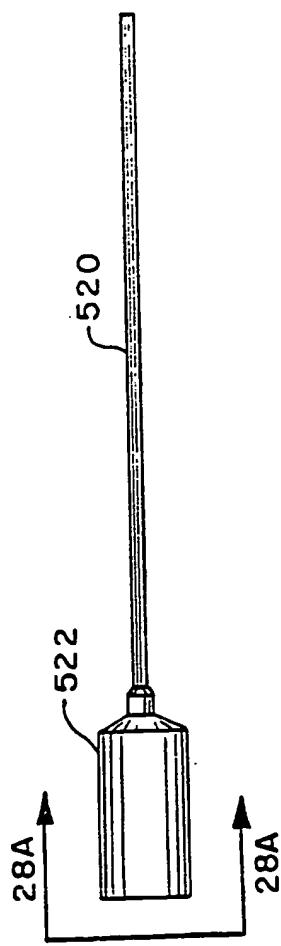


FIG. 28A

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FIG. 31

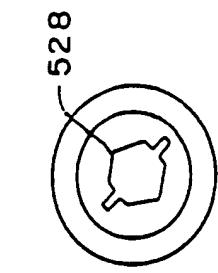
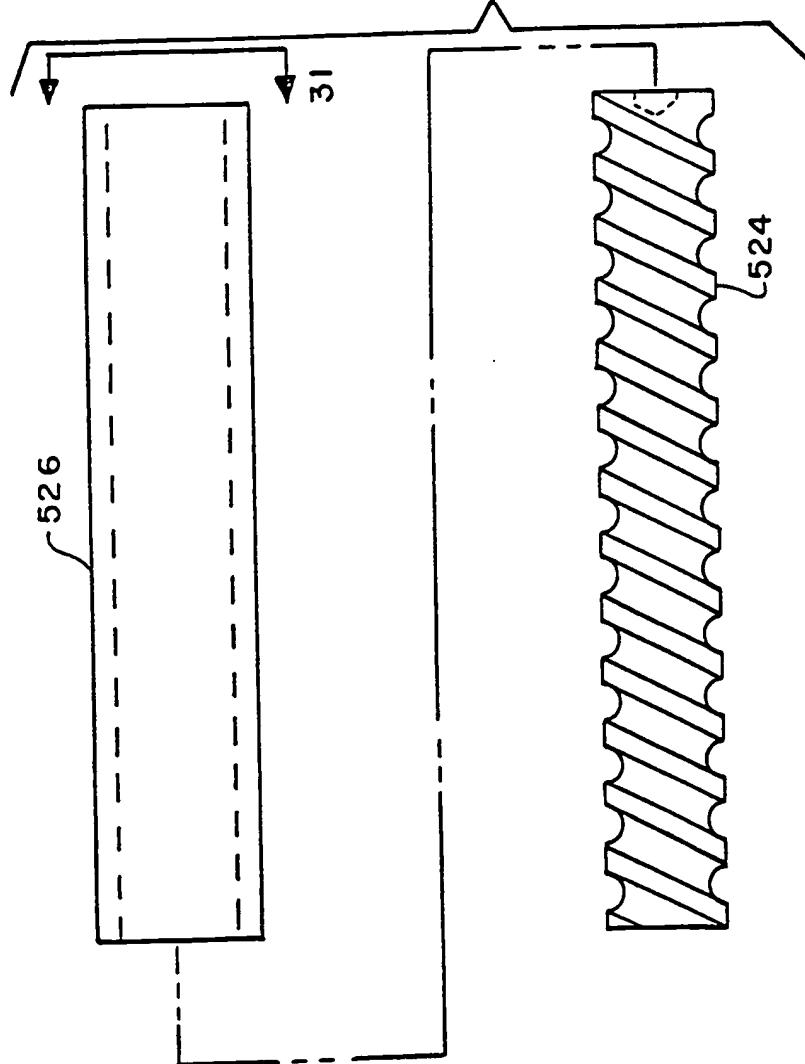
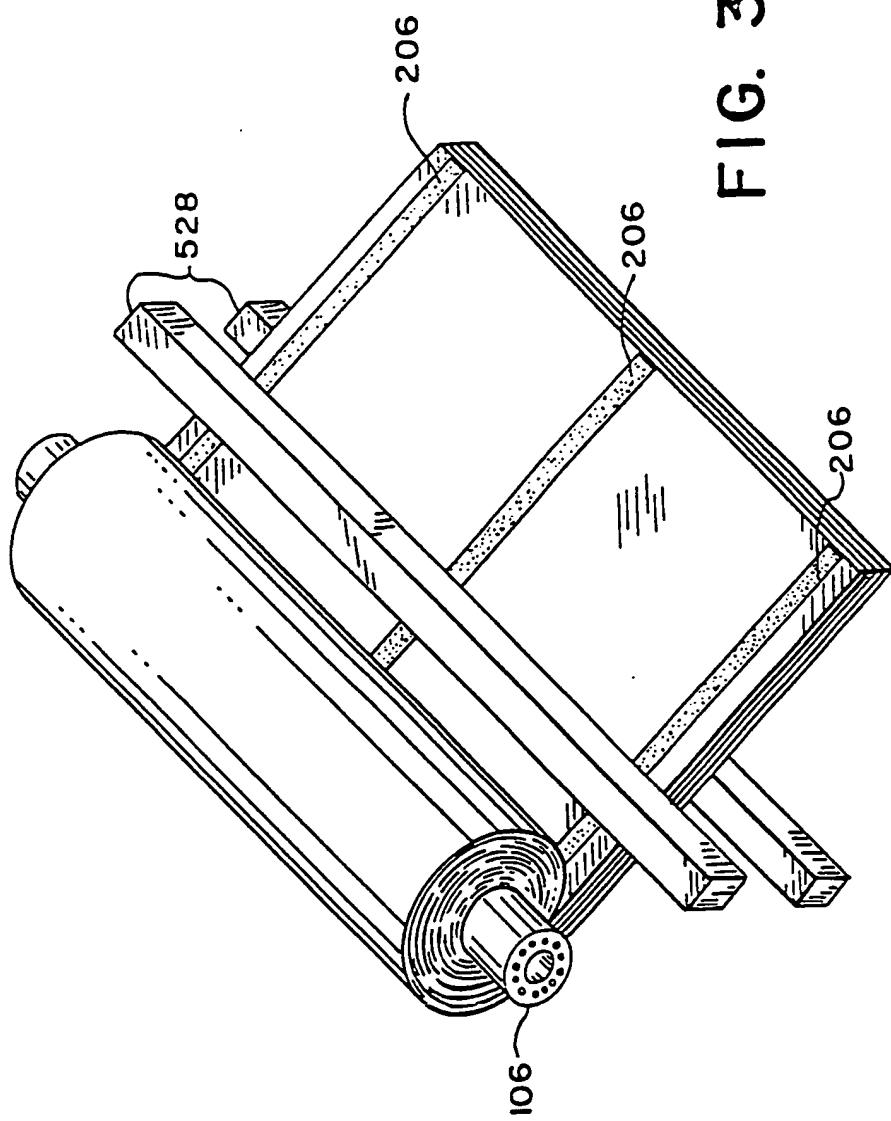


FIG. 30



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FIG. 32



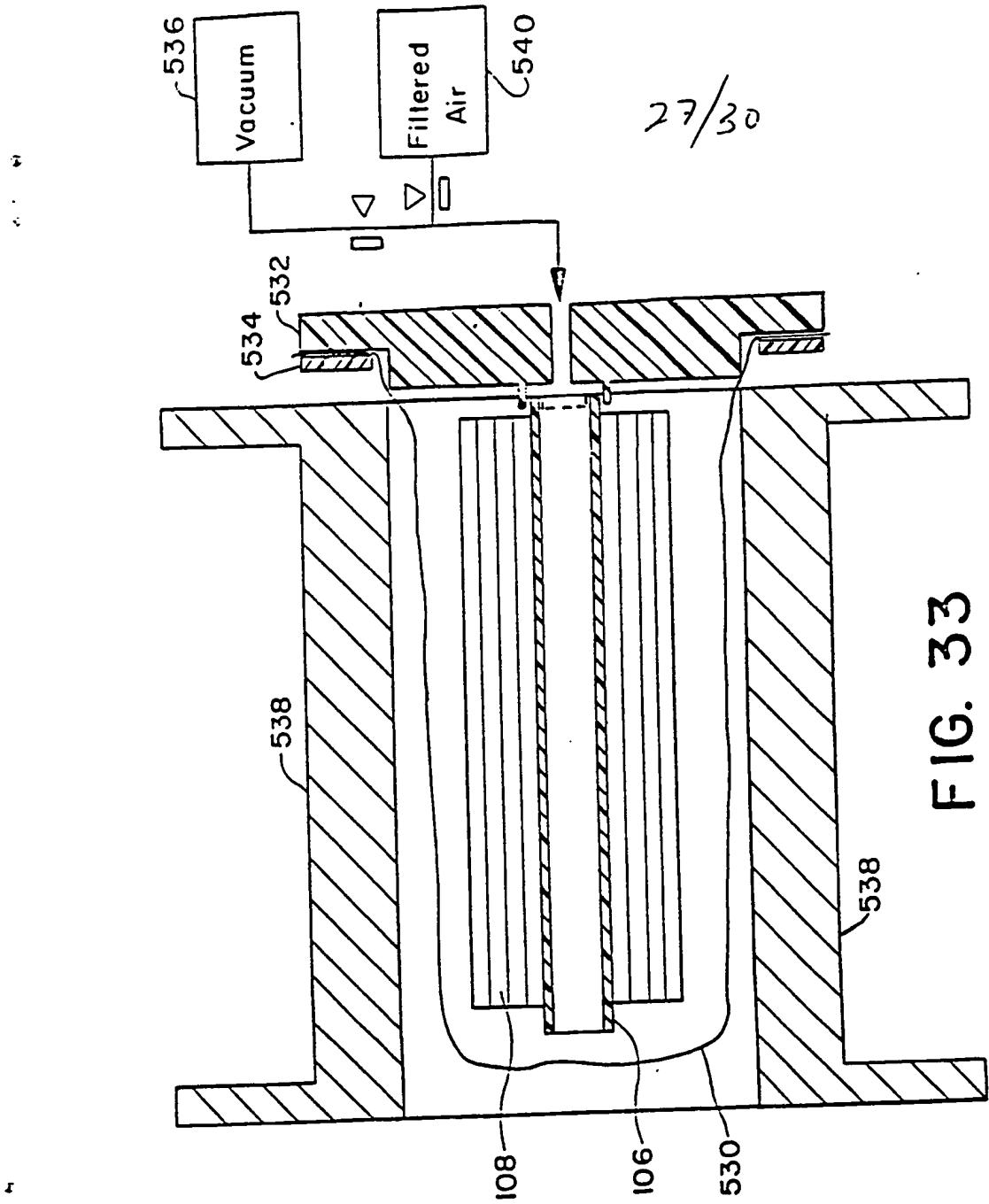


FIG. 33

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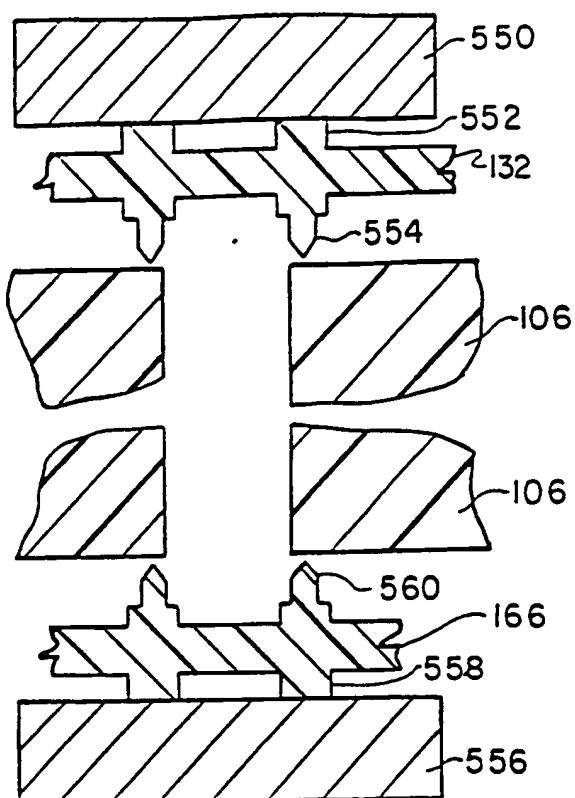


FIG. 34

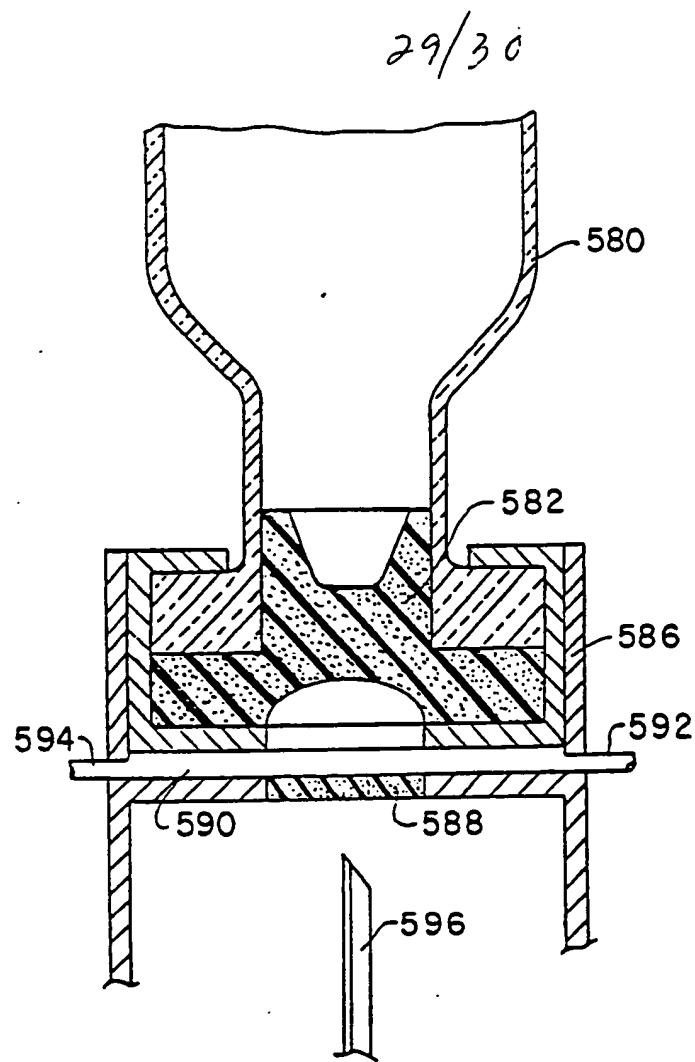


FIG. 35

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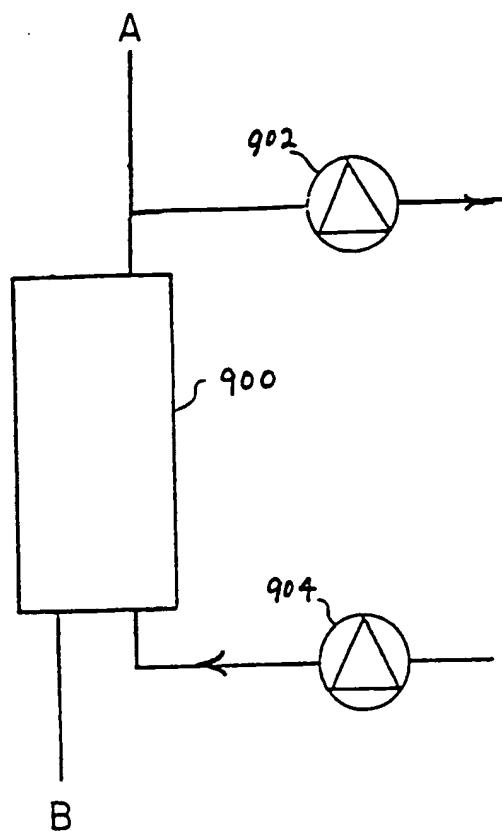


FIG. 36